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(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).

(72) Inventor: FUMIYAMA, Hideo; 3-6-2 B, Setagaya-ku, Tokyo 155-0032 (JP).

(74) Agents: VINITSKAYA, Lena et al.; Baxter Healthcare Corporation, P.O. Box 15210, Irvine, CA 92623-5210 (US).

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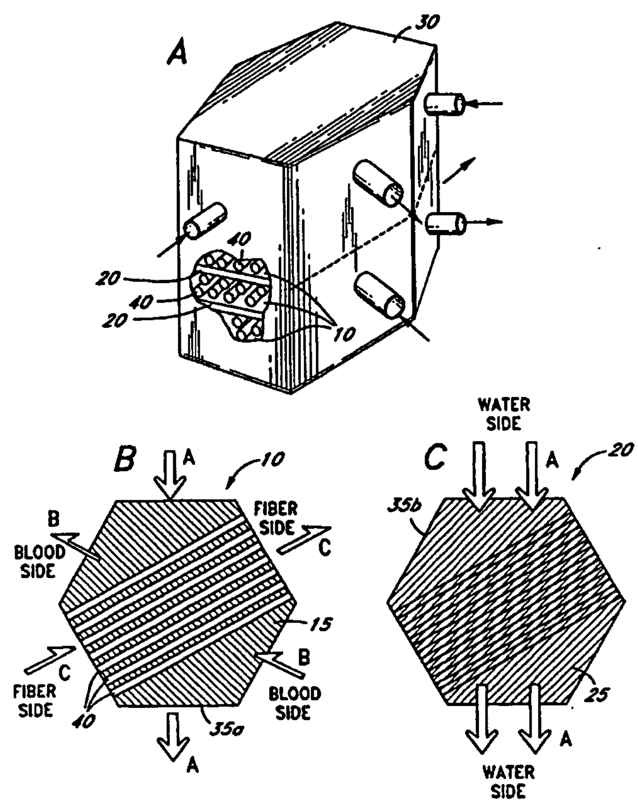
(54) Title: INTEGRATED MODULAR OXYGENATOR

(57) Abstract

A fluid oxygenator having gas exchange and heat transfer functions is constructed of one or more modules which can be combined to provide varying flow capacities. The modules each include blood (10), water (20), and gas paths (10) sealed from each other. The gas paths (10) may be defined by hollow gas exchange fibers (40) traversing through the blood paths (10) with open ends sealed from both paths (10). The blood and water paths (10) are defined by a plurality of heat transfer walls which are in contact with blood on one side and water on the other. An outer housing (30) encloses path-defining walls and potting material and designed in order to minimize prime volume. Two or more identical housings may be connected with a single overall inlet and outlet. A method of selecting an appropriately sized modular oxygenator is also provided, as well as various methods of construction.



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INTEGRATED MODULAR OXYGENATOR

Field of the Invention

This invention relates to integrated blood oxygenators for supplying oxygen to and removing carbon dioxide from blood, and, more particularly, to integrated modular blood oxygenators allowing simplified adjustment of the prime volume by combining modules, and methods of assembling such oxygenators.

Background of the Invention

Blood oxygenators are used when a patient's lungs are out of action during open-heart surgery, or when the lungs are impaired due to disease or trauma. Blood oxygenators take over the functions of the natural lungs by supplying oxygen to blood and removing carbon dioxide therefrom to keep the patient alive. Oxygenators are also used to condition other bodily fluids, such as cerebro-spinal fluid.

Blood oxygenators are of several types, including the bubble type in which oxygen is bubbled through the blood in direct contact therewith, and the membrane type in which a semi-permeable membrane separates the blood from the gas. The oxygenator of the present invention is categorized as a membrane type oxygenator in which blood and gas paths are separated by a membrane through which oxygen passes into the blood and carbon dioxide passes from the blood and into the gas stream. The oxygenator of the present invention preferably utilizes as membranes a large number of gas exchange fibers each of which is selectively permeable to allow diffusion of oxygen and carbon dioxide therethrough. Furthermore, the present oxygenator is integrated with a heat transfer device as opposed to being a stand-alone unit with a separate heat exchanger. Integrated membrane type oxygenators should be constructed so as to provide isolation among the water, gas and blood paths.

Because of the complexity and attendant cost of previous membrane oxygenators, and the lack of a truly modular oxygenator, there is a need for a cost-efficient design which enables rapid adaptation to varying performance and prime volume requirements and is highly efficient in blood/gas exchange.

Summary of the Invention

Therefore, it is an object of the present invention to provide an improved modular blood oxygenator with a simple structure and low cost.

It is another object of the present invention to provide an improved modular blood oxygenator having a plurality of easily combinable oxygenator modules to meet the size of the patient.

It is a further object of the present invention to provide a modular blood oxygenator of improved performance and simplified structure while achieving high reliability including isolation among water, blood and gas paths.

It is a further object of the present invention to provide a modular blood oxygenator with high gas exchange rates and low priming volume.

It is a further object of the present invention to provide a blood oxygenator wherein a number of water paths and blood/oxygen paths are alternately stacked together to form an oxygenator module.

It is a further object of the present invention to provide a modular blood oxygenator wherein the alternating water and blood/oxygen paths are separated by heat transfer substrates which are substantially similar in shape.

It is a further object of the present invention to provide a modular blood oxygenator wherein box type water units are used to flow water therein and blood/oxygen paths are formed on the outer surfaces of the water units.

It is a further object of the present invention to provide a modular blood oxygenator wherein a plurality of elongated pipes are grouped in parallel and gas

exchange fibers are arranged either within or outside of the pipes.

The present invention provides an integrated modular fluid oxygenator, having a plurality of independently functional oxygenator modules operatively attached together. Each module includes a housing with fluid inlet and outlet ports, gas inlet and outlet ports, and water inlet and outlet ports. The modules each include internal flow paths to facilitate oxygenation and heat regulation of the fluid, and when the modules are operatively attached together, the internal flow paths of the respective fluids for each module are in flow communication.

In accordance with a preferred form of the present invention, each module comprises a subassembly defined by a plurality of fluid impermeable heat transfer walls each having a water contact side and a fluid contact side. The heat transfer walls each defines a fluid path on the fluid contact side and a water path on the water contact side, wherein the fluid paths and the water paths are sealed from each other. The subassembly further includes a plurality of gas paths defined by semi-permeable gas exchange membranes in contact with fluid in each of the fluid paths. Each gas path has an open inlet end and an open outlet end, both of which are sealed from the fluid paths and the water paths. An outer housing encloses the subassembly and includes a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and a gas outlet. A fluid inlet plenum is in flow communication with the fluid inlet and the fluid paths, and a fluid outlet plenum is in flow communication with the fluid outlet and the fluid paths, the fluid inlet and outlet plenums being positioned with respect to each fluid path to direct fluid flow therethrough when fluid is introduced to the fluid inlet. A water inlet plenum is in flow communication with the water inlet and the water paths, and a water outlet plenum is in flow communication with the water outlet and the water paths, the water inlet and outlet plenums being positioned with respect to each water path to direct water flow therethrough when water is introduced to the water inlet. A gas inlet plenum is in flow communication with

the gas inlet and the inlet ends of the gas paths, and a gas outlet plenum is in flow communication with the gas outlet and the outlet ends of the gas paths. Each module may independently function as an oxygenator, and two or more modules may be positioned adjacent one another to function together as an oxygenator with the respective fluid inlet and outlets, water inlet and outlets, and gas inlet and outlets configured to enable communication between respective fluid paths, water paths and gas paths of the two modules.

In one embodiment, the heat transfer walls comprise parallel planar portions of a series of spaced substrates each forming seals with the housing to separate alternating fluid and water paths. The housing may have a hexagonal cross-section taken in the plane of the substrate planar portions with three pairs of opposed sides, with each pair of inlet and outlet plenums for the fluid, water, and gas paths being associated, respectively, with one of the pairs of opposed sides. The housing may have a box shape, with the substrates arrayed within, a potting compound providing sealed inter-connections between the substrates and housing and between adjacent substrates, and the plenums defined between the substrates and the housing partly by the inter-connecting potting compound.

In another embodiment, the heat transfer walls comprise opposed panels of a plurality of box structures, the oxygenator including a stack of spaced box structures. The water contacting sides of the heat transfer walls are defined by the internal surfaces of the opposed panels and the fluid contacting sides of the heat transfer walls are defined by the external surfaces of the opposed panels. Spacers may be provided between the box structures to form gaps defining the fluid paths, wherein the gas paths are defined within hollow gas exchange fibers extending through each fluid path.

In another embodiment, the heat transfer walls comprise walls of elongated pipes, the pipes being spaced apart within the housing. Either the fluid paths are defined within each pipe, and the water paths are defined by the

spaces formed between the pipes, or the water paths are defined within each pipe, and the fluid paths are defined by the spaces formed between the pipes.

In a further embodiment, the independently functional oxygenator modules may connect to each other at juxtaposed straight sides, and the inlets and outlets for each of the fluid, water, and gas flow paths are connected in series external to the housings. Alternatively, the inlets and outlets for each of the fluid, water, and gas flow paths are connected in series through openings in the juxtaposed straight sides. In the latter case, the oxygenator modules may have elongated hexagonal exteriors, with six straight sides including break-out panels in at least two for forming the openings. The fluid inlets and outlets may be cooperatively connected so that the fluid flow is in series through the hexagonal modules, and wherein there are an odd number of modules connected in a triangular arrangement with the fluid inlet to the first of the modules in series being elevated above the fluid outlet to the last of the modules in series.

In a still further embodiment, the independently functional oxygenator modules may be generally parallelepiped in exterior shape and are stacked vertically and connected to each other at juxtaposed horizontal sides. The fluid inlets and outlets are desirably cooperatively connected so that the fluid flow is in series downward through the modules.

Brief Description of the Drawings

Figure 1A is a perspective view of an oxygenator having a housing wherein a stack of blood/oxygen path-defining members and water path-defining members are provided.

Figure 1B is a schematic plan view of a blood/oxygen path-defining member of the oxygenator of Figure 1A.

Figure 1C is a schematic plan view of a water path-defining member of the oxygenator of Figure 1A.

Figure 2 schematically shows an inner structure of the oxygenator of Figure 1A where the blood/oxygen path-defining member and the water path-defining member are alternately stacked.

Figures 3A-3C and 3E are plan views of both blank and formed planar substrates for the blood/oxygen path-defining members and water path-defining members of the oxygenator of Figure 1A. Figure 3D and 3F are elevational views of formed substrates showing protrusions bent out of the plane of the substrates.

Figures 4A and 4B are perspective views showing a more detailed inner structure of the oxygenator of the present invention.

Figures 5A and 5B are schematic diagrams showing a basic process of potting the predetermined sides of the stacked structure of Figures 4A and 4B.

Figure 6 shows a process of cutting off a portion of bonded area of the stacked structure to create an inlet and outlet for the corresponding path.

Figure 7 is a plan view showing the stacked path-defining members placed in the housing of Figure 1A.

Figures 8A and 8B are perspective views showing examples of a blood inlet/outlet manifold of the oxygenator of Figure 1A.

Figure 9A is a more detailed perspective view showing an example of internal structure of the oxygenator using the blood inlet/outlet of Figure 8A.

Figure 9B is a cross-sectional view of the blood inlet/outlet of Figure 8A.

Figure 9C is a more detailed perspective view showing an example of internal structure of the oxygenator using the blood inlet/outlet of Figure 8B.

Figure 9D is a cross-sectional view of the blood inlet/outlet of Figure 8B.

Figure 10A and 10B are schematic front and top cross sectional views, respectively, of exemplary oxygenator path-defining members of the present invention having a nearly hexagonal shape in plan view.

Figure 11A is a plan view of a substrate for use in constructing a plate-type modular oxygenator.

Figures 11B-11C are plan views showing two designs for reducing the oxygenator priming volume by modifying the shape of the substrate of Figure 11A.

Figure 12A is a plan view showing a substrate which combines the low priming volume aspects of the substrates of Figures 11B and 11C.

Figure 12B is a schematic elevational view of a low priming volume oxygenator which combines a number of the substrates of Figure 12A.

Figure 13 is a schematic elevational view of a modular oxygenator which shows a modification from Figure 12B to further decrease the priming volume.

Figures 14A-14C are plan views of successive substrates to be used in the oxygenator shown in Figure 13.

Figure 15 is a perspective view showing an exemplary reduced prime oxygenator of the present invention having the modified hexagonal-shaped path-defining members shown in Figure 14A-C (the oxygenator shown on its side and partially cutaway to expose the substrates within).

Figure 16A is a horizontal cross sectional view of the reduced prime oxygenator of Figure 15 showing a blood/oxygen path-defining member.

Figure 16B is a horizontal cross sectional view of the reduced prime oxygenator of Figure 15 showing a water path-defining member.

Figure 16C is a partial cross sectional view showing a sealing arrangement between an outer housing and the stack of blood/oxygen and water path-defining members of the oxygenator of Figure 15.

Figures 17A-17J are cross sectional views showing the process of forming a plate oxygenator of the present invention.

Figures 18A-18C shows cross sectional views showing different degrees of potting depth around the blood inlet/outlet area of the oxygenator.

Figure 19A is a perspective partially phantom view of an exemplary embodiment of a water path-forming box representing a portion of a modular

blood oxygenator in accordance with the present invention.

Figure 19B is a top plan view of the box type water path-defining member of Figure 19A.

Figure 19C is a cross sectional view of the box type water path-defining member of Figure 19A.

Figure 19D is a bottom plan view of the box type water path-defining member of Figure 19A.

Figure 20 is a perspective exploded view of a number of stacked water path-forming boxes prior to assembly.

Figures 21-23 are cross sectional views showing potting and assembling methods of the box type water path-defining members of the present invention.

Figure 21 is a cross sectional view of the blood/oxygen path formed between two water path-forming boxes.

Figure 22 is a cross sectional view through the box type water path-defining member.

Figure 23 is a cross sectional view of the stacked path-defining members installed in a housing after the processes of Figure 21 and 22.

Figure 24A is a perspective view of another exemplary embodiment of a water path-forming box of the present invention having upper and lower recesses to mount the gas exchange fibers therein.

Figure 24B is a perspective exploded view of the water path-forming box of Figure 24A showing a container portion with a top wall removed.

Figures 25A-25C are perspective views showing a process of mounting sheets of gas exchange fibers on an upper recess of the box type water path-defining member of Figure 24.

Figure 26 shows a step where a second water path-forming box is placed on the first box and wherein the sheets of gas exchange fibers in the upper recess of the first box fit within the lower recess on the second water box to form a

blood/oxygen path therebetween.

Figure 27 is an exploded perspective view of a stack of box type water path-defining members of Figure 24 forming blood/oxygen paths therebetween and a housing used for potting purposes.

Figure 28 is a perspective view of the stacked path-defining members in Figure 27 inserted in the potting housing shown in phantom.

Figure 29 is identical to Figure 28 and illustrates the process of introducing potting material between the assembly of stacked path-defining members and potting housing to cover the inlets and outlets of the blood/oxygen and water paths.

Figure 30 illustrates the subassembly of stacked path-defining members removed from the potting housing with ends of the potting material sheared off to expose the inlets and outlets of the blood/oxygen and water paths, forming an oxygenator core.

Figure 31 is a perspective view of a modular oxygenator housing for receiving the oxygenator core.

Figure 32 is a perspective view of the oxygenator core installed in the oxygenator housing shown in phantom and showing an exploded closure lid.

Figure 33 is a perspective view of the oxygenator core assembled in the housing with connection tubes installed in inlet/outlet conduits.

Figure 34A is a perspective exploded view of a dual module oxygenator with coupled housings and a single closure lid.

Figure 34B is a perspective view of the assembled dual module oxygenator of Figure 34A with connection tubes installed in inlet/outlet conduits.

Figure 34C is a perspective view of an assembled three module oxygenator similar to the dual oxygenator of Figure 34B.

Figure 35 is a perspective view of a water path-forming box which is similar to the example of Figure 24 but which includes fiber spacing ribs in the

blood/oxygen path-forming recesses.

Figure 35B is a perspective view of the ribbed box type water path-defining member with a top wall removed exposing inner reinforcing struts.

Figures 36A-36D are perspective views showing an exemplary mold process for producing the ribbed box type water path-defining member of Figure 35A.

Figures 37A-37C are horizontal sectional views corresponding to the exemplary mold process steps shown in Figures 36A-C.

Figures 38 and 39 illustrate a process of mounting alternating sheets of gas exchange fibers over one of the blood/oxygen path-forming recesses of the water path-forming box of Figure 35.

Figure 40 is a schematic perspective view of fluid flow through a modular pipe oxygenator with gas exchange fibers installed longitudinally in a plurality of spaced, parallel hexagonal pipes to form blood/oxygen paths therein.

Figure 41 is a schematic perspective view of a second fluid flow through a modular pipe oxygenator where the gas exchange fibers are arranged longitudinally outside of the pipes and blood flows transversely between the pipes, while water is flowed in the pipes to form water paths therewithin.

Figure 42 is a schematic perspective view of a third fluid flow through a modular pipe oxygenator where the gas exchange fibers are arranged longitudinally outside of the pipes and blood flows radially inward to a central channel between the pipes while water is flowed in paths defined within the pipes.

Figure 43 is one exemplary construction of the modular pipe oxygenators of Figures 41 or 42 wherein sheets of the gas exchange fibers are aligned longitudinally outside of the pipes.

Figures 44A-F illustrate process steps for assembling and potting a modular pipe oxygenator.

Figure 45A is a cross sectional view of a modular pipe oxygenator formed

with two modules in series having inlets and outlets in fluid communication.

Figure 45B is a perspective view of the two module pipe oxygenator of Figure 45A.

Figure 46A is a cross sectional view of a modular pipe oxygenator formed with three modules connected in a triangle with inlets and outlets in fluid communication and having a single flow path therethrough.

Figure 46B is a perspective view of the three module pipe oxygenator of Figure 46A.

Figure 47A is an exploded cross-sectional view of a further version of a modular pipe oxygenator.

Figure 47B is an assembled cross-sectional view of the modular pipe oxygenator of Figure 47A.

Figure 48A is a cross-sectional view of two modular pipe oxygenators of Figure 47A coupled together in series.

Figure 48B is a cross-sectional view of three modular pipe oxygenators of Figure 47A coupled together in series.

Detailed Description of the Preferred Embodiments

The integrated modular blood oxygenator of the present invention comprises a plurality of water and blood/oxygen channel- or path-defining members combined in one or more modules depending on the performance and prime volume required. The respective paths are separated by a plurality of heat transfer walls which are in direct contact with the blood and water on opposite sides. The water flowing through the water paths transfers heat with the blood through the walls in the adjacent blood/oxygen paths to maintain proper blood temperature. The blood/oxygen paths desirably include a number of gas exchange fibers for circulating gas therein, but may also incorporate other gas exchange mediums. The ability to quickly modify the capacity of the oxygenator in the manufacturing assembly stage from standard components has heretofore not been

available. Furthermore, various embodiments of the present invention enable great efficiency of heat transfer and blood/gas interaction, which reduces the size of any one capacity oxygenator.

Definitions

In general terms, the present invention provides an integrated fluid oxygenator constructed of one or more modules each including fluid and water paths sealed from each other and gas exchange fibers traversing through the fluid paths with open ends sealed from both paths. The paths are defined between a plurality of heat transfer walls which are in contact with fluid on one side and water on the other. As will be described below, the walls may be formed with parallel plates, spaced boxes, elongate pipes or other suitable structures. An outer housing encloses a subassembly of path-defining walls and potting material and provides inlets and outlets for the fluid, water and gas. The respective inlets and outlets are in fluid communication with plenums which are in turn open to the paths.

The function of the oxygenators described herein is to replenish fluids with particular gaseous components while transferring heat to or from the fluid. Thus, the traditional use of oxygenators is to recondition blood in an extracorporeal circuit by increasing the concentration of dissolved oxygen while decreasing the concentration of dissolved carbon dioxide. However, other bodily fluids may also be conditioned using the oxygenators described herein. For example, recent advances in treating strokes in children have involved the removal and oxygenation of the patient's spinal fluid, along with some heat conditioning. The volume of spinal fluid which can be safely routed extracorporeally is generally less than the safe amount of blood, and thus small prime volume oxygenator units are required. In short, the present invention may be beneficial for use with a number of fluids other than blood.

A "module" is formed by combining a subassembly of path-defining walls and a housing, with potting material between the walls and housing used to seal respective paths from each other, and with inlet-to-path and path-to-outlet communicating plenums formed therebetween. A "plenum" may be described as a space in fluid communication with a fluid inlet or outlet, and with all of the respective paths for that fluid. Of course, however, the gas plenums are in communication with either the open inlets or outlets of the gas exchange fibers. When two or more "modules" are combined, their respective plenums are desirably placed in series communication, so that a single flow path for each fluid extends through the aggregate oxygenator. Alternatively, of course, some division of the flow through parallel paths is envisioned, and within the scope of the present invention.

The term "gas exchange fibers" pertains to individual fibers or to mats of connected fibers. The gas exchange fibers are tiny and flexible pipes having a preferred diameter of 0.2-0.4mm and a micro-porous construction so as to function as membranes, wherein oxygen to the blood and carbon dioxide from the blood pass therethrough. A monofilament may be helically wound around individual fibers to provide spacing for blood flow between stacked fibers. Alternatively, fiber mats are produced in single layer sheets of multiple parallel hollow fibers which can easily be stacked or otherwise grouped to form plural layers of multiple fibers. Some fiber mats include a weave of filaments connecting the individual fibers which may act to space adjacent fiber mat layers. Other fiber mats do not include such weave, and will necessarily by more closely packed with adjacent layers. One manufacturer of fiber mats suitable for use in the oxygenators of the present invention is Akzo Nobel N.V. of Arnhem, Netherlands.

Alternatively, the present invention may also benefit oxygenators with planar gas exchange mediums, as opposed to hollow fibers. In such oxygenators,

a planar or otherwise nontubular semi-permeable gas exchange member separates a blood path from a gas flow path. Therefore, the term "gas exchange medium" is intended to encompass both hollow fibers and other mediums known in the art, including planar members, which separate blood and gas paths.

Plate-Type Modular Oxygenators

Figure 1A illustrates an oxygenator "module" of the present invention having a housing 30 within which are installed a stack of alternating blood/oxygen paths 10 and water paths 20 (schematically shown in cutaway). The housing 30 may be formed in a number of peripheral shapes in plan view, but is desirably a polygon, and more preferably a six-sided hexagon, to accommodate the stack of blood/oxygen paths and water paths which are defined between six-side polygonal planar substrates. Of course, other arrangements of substrates and housing shapes are contemplated. Figure 1A also shows water, blood and gas inlet and outlets which are in communication with respective passages in the housing. Each inlet/outlet of the passage of the water, blood and gas is located normal with respect to one of the six sides of the hexagonal housing. This facilitates manufacture by clearly orienting each inlet/outlet perpendicularly with respect to a flat housing surface. The horizontal dashed line across the mid-point of the housing indicates a dividing plane between internal regions of the housing, wherein structure (not shown) may be provided to induce a U-shaped flow path for the fluid and/or water enabling the corresponding inlet and outlet to be positioned on the same side of the hexagonal housing.

Figure 1B is a schematic plan view of a blood/oxygen path 10 of the present invention. The blood/oxygen path 10 is formed within a space created between two spaced, parallel substrates, one of which is shown at 35a, having an equilateral hexagonal shape in plan view. A number of gas exchange fibers 40 are aligned in parallel with and between the opposed substrate surfaces in the

direction of arrow **C** (from fiber side to fiber side). Oxygen flows into the gas exchange fibers 40, and blood 15 flows between the spaced substrates 35a in the direction of arrow **B**, whereupon oxygen and carbon dioxide diffusion occurs through the micropores in the tubular walls of the fibers. Thus, the walls of the fibers 40 function as gas exchange mediums between the internal gas paths and external blood path.

Figure 1C is a schematic plan view of the water path 20 of the present invention. The water path 20 is formed within a space created between two spaced, parallel substrates, one of which is shown at 35b, having an equilateral hexagonal shape in plan view. The water 25 flows between the opposed substrate surfaces in the direction of arrow **A**. Each blood/oxygen path 10 is separated from the water flowing in path 20 by the substrates 35 and by potting between the substrate edges and the housing 30.

Gas flows in the direction **C** while diffusing through the gas exchange fibers 40 into the blood flowing in direction **B** and receiving the carbon dioxide from the blood. The water in the path 20 streams in the direction of the arrow **A**. Therefore, the directions of the blood, gas and water are oblique to one another, although in parallel planes, and originate/terminate at corresponding straight sides of the hexagonal substrate so that the leakage among them can be easily avoided, as will be explained later.

The water path 20 of Figure 1C and the blood/oxygen path 10 of Figure 1B are alternately stacked to achieve high efficient heat transfer therebetween. Preferably, the water path 20 and the blood/oxygen path 10 are alternately stacked immediately adjacent one another as shown in Figure 2 so that a blood/oxygen path 10 is formed above a substrate 35a and below a substrate 35b, and a water path 20 is formed above the same substrate 35b and below the next substrate 35a. To ensure efficient heat transfer between the blood/oxygen path 10 and the water path 20, the substrates are desirably made of a material with good thermal

conductivity, preferably stainless steel, although other materials may suffice.

Figures 3A-3F illustrate the substrates 35a for the blood/oxygen path 10 and the substrates 35b for the water path 20 of the present invention both in the blank stage and after a forming operation. Preferably, stainless steel is used as a material for the substrates because of its high thermal conductivity and excellent bio-compatibility. A further advantage in using the stainless steel is its simplicity in the cutting and bending process. If stainless steel is used, the thickness of each substrate should be sufficient to provide structural strength to avoid undue deflection from internal fluid pressures, yet be thin enough for the desired rate of heat transfer therethrough.

Figure 3A shows a sheet of stainless steel blank cut in a shape to be used for the substrate 35b for the water path 20. The cutout substrate 35b has arm like protrusions 36b at the two opposite sides. Figure 3B shows a sheet of stainless steel cut in a shape to be used for the substrate 35a for the blood/oxygen path 10. The cutout substrate 35a has blade like protrusions 36a at the two opposite sides. The flat sheet of substrates 35b and 35a of Figures 3A and 3B, respectively, are processed as shown in Figures 3C-3F. The arm like protrusions 36b of the substrate 35b are bent in the upward direction in a manner shown in the plan view of Figure 3C and the front view of Figure 3D. Similarly, the blade like protrusions 36a of the substrate 35a are bent in the upward direction in a manner shown in the plan view of Figure 3E and the front view of Figure 3F. The protrusions 36b and 36a are bent in such a way that the angle between each of the protrusions and the flat surface of the substrate is slightly greater than 90 degrees, i.e., the span between the upper portions is wider than that between the lower portions of the protrusions 36a or 36b. The protrusions 36b and 36a are also seen in Figures 4A and 4B.

Figures 4A and 4B are perspective views showing an inner structure of the oxygenator of the present invention including the stacked substrates. The

example of Figures 4A and 4B show only three paths, although in an actual oxygenator, a larger number of paths may be stacked together. An upper blood/oxygen path 10_a is stacked on a water path 20_a which is stacked on a lower blood/oxygen path 10_b. On each of the blood/oxygen paths 10a and 10b, the gas exchange fibers 40 are installed in the direction C of Figure 1B.

Because the angle of bend of the protrusions 36a and 36b, which is slightly larger than 90 degrees with respect to the planar main body of the substrates 35a and 35b, upper substrates will fit in and be cradled by the lower substrates as shown in Figures 4A and 4B. The straight sides of the six-sided polygon enable a stable stacking in this manner. The bent protrusions 36a and 36b contact each other to form an opening 26 for the water path 20_a (i.e., between the substrates defining the water path). To maintain the opening 26, a rectangular plug 27 whose outer end is preferably closed will be inserted therein, as shown in Figure 4B, prior to a potting process. The plug 27 prevents potting material from oozing into the water path 20, and can easily be removed to expose a water inlet/outlet to the path.

Plate-Type Modular Oxygenator Potting Process

Figures 5A and 5B are schematic diagrams showing steps for potting the stacked path-defining substrates of Figures 4A and 4B, although the potting process is preferably carried out by a potting machine where the set of stacked substrates is rotated in sequence and with accuracy. In an alternative arrangement, a centrifugal potting drum is used with the stacked substrates placed concentrically therein and allowed to rotate therewith so that the potting material is present only at the inner edges of the drum by virtue of centrifugal forces and therefore contacts and adheres to the outer sides of the stack at these locations.

To better illustrate the construction of the oxygenator, details of a generic potting process are seen in Figures 5A and 5B. Potting on the side of the stacked

substrates 35 corresponding to the inlet and outlet of the water paths 20 is shown in Figure 5A. Predetermined sides having the plugs 27 are dipped in the potting material 50 which is typically polyurethane. The thickness of potting, i.e., the depth of dipping the end of the water path in the potting material is important to establish sufficient isolation among the paths, and will be explained later in more detail. The potting process for the side of the stacked substrates corresponding to the inlet and outlet of the blood/oxygen paths 10 is shown in Figure 5B. The ends of the gas exchange fibers 40 are so arranged that the potting material 50 will not go into the fibers (i.e., provided long enough to drape out of the potting container). Alternatively, a pre-potting operation is performed in which the fibers are severed close to the stacked paths and dipped to a short distance into the potting material to prevent further passage of potting material in the main potting operation.

After the potting process, as shown in Figure 6, the sides of the now potted stacked substrates 35 are cut in parallel with the corresponding sides of the substrate. Each of the rectangular plugs 27 fitted in the openings 26 at both ends of the water path 20 are removed to establish an inlet and an outlet for the water to pass therethrough. Similarly, in each blood/oxygen path 10, the ends of the gas exchange fibers 40 are severed and left open to the outside of the potting material to establish inlet/outlet ports for gas to pass therethrough. Notice two opposed sides are left unpotted or are otherwise opened to form blood inlet/outlets.

Figure 7 is a plan view after the stacked, potted and cut paths are fit in the housing 30 of Figure 1A. At each corner, potting or a seal 42 is provided between the housing 30 and the stacked paths to complete the isolation among the water, gas and blood paths. The seals 42 extend the height of the housing to span all of the stacked paths. More detail with regard to this type of seal is explained later with reference to Figures 9A-9D.

Blood Inlet/Outlet Manifolds

Figure 8A is a perspective view showing an example of blood inlet/outlet manifold 16 of the present invention. Although the example of Figure 8A is illustrated as an inlet to channel blood from a patient into the oxygenator, the same design structure is used as an outlet for returning the blood from the oxygenator to the patient. The blood inlet/outlet manifold 16 is formed of a main plenum 17 having a port 18 for receiving the blood from the patient and a plurality of regularly spaced rectangular openings 19a-19n opening to one side of the main plenum 17. Short hollow rectangular ducts 21 define the openings 19. The thickness of the ducts 21 is so arranged to fit closely within the blood/oxygen paths 10 between two substrates. Thus, when blood is introduced in the main plenum 17, an equal amount flows perpendicularly and substantially simultaneously through the openings 19 into each of the blood/oxygen paths 10. To facilitate even distribution of blood between the openings 19, the ports 18 for the inlet and outlet manifolds 16 are open to opposite ends of the stacked paths. The plenum 17 may be constructed in a variety of sizes depending on flow requirements, and preferably matches the ID of tubing connecting the oxygenator to the patient, for example 0.1875-0.375 inch (4.76-9.53 mm)

Figure 8B is a perspective view showing another example of blood inlet/outlet manifold 16' of the present invention which includes leak prevention structure. In this example, each of the plurality of ducts 21' has a wedge like shape while the openings 19_a'-19_n' remain rectangular. The flared ducts 21' provide structure which facilitates a potting process and helps prevent leaks from voids inadvertently formed in the potting material. This feature is described below with respect to Figures 18A-C.

Figure 9A is a perspective view showing internal structure of the oxygenator of the present invention wherein the blood inlet/outlet manifold 16 of Figure 8A is placed in fluid communication with the blood/oxygen paths 10 to circulate the blood therethrough. Each of the ducts 21 is inserted into a

blood/oxygen path 10 so that the openings 19 direct blood past the bundle of gas exchange fibers 40 therein. As noted above, the height of the ducts 21 matches the height of the blood/oxygen paths 10, so that the ducts contact the substrates 35a and 35b.

Figure 9B is a horizontal cross-sectional view of the blood manifold 16 as molded within the oxygenator showing the potted areas cross-hatched. The thickness of the potted areas is sufficiently large to seal the plenum 17 and duct 21 to the stack of path-defining substrates, while the openings 19 are left open to the blood/oxygen space in which are bundled the fibers 40.

Figure 9C is a perspective view showing another example of internal structure of the oxygenator using the blood inlet/outlet manifold 16' of Figure 8B. As with the first embodiment, each of the ducts 21' is inserted in the blood/oxygen path 10 so that the openings 19' direct blood past the bundle of gas exchange fibers 40 therein. Again, the height of the ducts 21' matches the blood/oxygen path 10, so that the ducts contact the substrates 35a and 35b.

Figure 9D is a horizontal cross-sectional view of the blood inlet/outlet manifold 16' of Figure 8B as molded within the oxygenator and showing the thickness of the potted areas cross-hatched. The potting is sufficient to prevent leakage between the blood, gas, and water paths.

<u>Reduced Prime Plate-Type Modular Oxygenators</u>

Figure 10A and 10B are schematic front and top cross sectional views, respectively, of the oxygenator paths having a nearly equilateral hexagonal shape in plan view. The water paths 20 and the blood/oxygen paths 10 are alternately stacked as shown in Figure 10A to control the temperature of the blood streaming through the blood/oxygen paths. One of the requirements of an oxygenator is a smaller priming volume to reduce blood deficiency related trauma to the patient. In the example of Figure 10A and 10B, equilateral triangular portions on the right

and left indicate "unused" flow spaces in each layer of the oxygenator, meaning spaces where blood is not in contact with the gas exchange fibers 40. The blood in these areas is not contributing to the oxygenation process, which negatively affects the amount of dilution of the patient's blood.

Figures 11A-11C are cross sectional views showing two approaches to reducing the relative priming volume according to the present invention. First, the nearly equilateral hexagonal shape of Figure 11A is modified by lengthening the middle portion as shown in Figure 11B to increase the surface area of the oxygenating function relative to the overall volume in each layer. Although the unused flow space not in contact with the gas exchange fibers is the same as that of the structures of Figure 11A, the area of blood in contact with the fibers is significantly increased with respect to the unused flow space, which reduces the relative priming volume.

In the second approach, the nearly equilateral hexagonal shape of Figure 11A is skewed as shown in Figure 11C so that the triangular unused flow spaces are no longer equilateral. As a result, the triangular unused flow spaces of Figure 11C are smaller than the triangular unused flow spaces of Figure 11A whereas the surface area for the gas exchange fibers 40 is increased relative to the example of Figure 11A. Therefore, in the example of Figure 11C, the relative priming volume is also decreased, which reduces the amount of blood dilution.

Figures 12A and 12B show a substrate structure of the oxygenator module of the present invention which is a combination of the two examples of Figures 11B and 11C. Because of the increased length of the middle oxygenation portion, and a decreased unused flow space M, the relative priming volume is dramatically decreased from the original hexagonal module of Figure 11A. Again, this reduces the amount of blood dilution. Figure 12B is a schematic vertical cross sectional view of the oxygenator of the present invention having the structure of Figure 12A. As shown in Figure 12B, the water paths 20 and the blood/oxygen paths 10

of the same shape are alternately stacked together.

Figure 13 shows a further modification in the structure of the oxygenator from the example of Figure 12B. In Figure 13, although the horizontal cross sectional view is approximately the same skewed and lengthened six-sided figure as in Figure 12A, the ends of all but one substrate are bent so as not to be in the same plane as the middle portion. That is, the middle substrates **a** (representing a water path 20) are planar, while the upper and lower substrates (indicated by **b** and **c**) have unused flow spaces which are bent toward the middle. The blood inlet/outlet areas N in Figure 13 are thus shaped in a triangular manner rather than areas M of Figure 12 which have square shapes. Thus, the unused flow space is further reduced from the example of Figure 12 which, again, reduces the amount of blood dilution..

In the example of Figure 13, since each of the paths has a different shape from the others, the stainless steel substrates for such paths have varied shapes. These varied shapes are shown in Figures 14A-14C which give plan views of corresponding sheets of stainless steel to be used for the paths shown in Figure 13. For example, the stainless steel substrate of Figure 14A will be used for the central portion **a** of Figure 13. The stainless steel substrates of Figures 14B and 14C will be used for portions **b** and **c**, respectively. The stainless steel substrates of Figures 14B and 14C have gradually sharper triangular unused flow spaces so as to be bent in a manner to join with the ends of the other substrates near the vertical midpoint of the oxygenator, as shown in Figure 13.

Plate-Type Modular Oxygenator Function

Figure 15 is a perspective view showing the oxygenator of the present invention having the path-defining substrates of modified hexagonal shape shown in Figure 13. It should be noted that the view of Figure 15 is sideways from the earlier orientations shown, so that the substrates are in vertical planes and the

blood/oxygen and water paths are stacked horizontally. An outer housing 31 has, at its outside, a blood inlet 18_I and a blood outlet 18_O, a water inlet 28_I and a water outlet 28_O, and a gas (oxygen) inlet 38_I and a gas outlet 38_O. Since each of the inlets and outlets is provided on the sides of the hexagonal substrate different from the other sides, isolation from the other inlets and outlets can be achieved easily through the potting process as described above, and the sealing process of Figure 17. Alternatively, the inlet and outlet for any one of the fluid, water, or gas paths may be located on a common side, as with the embodiment of Figure 1.

Gas enters housing 31 at inlet 38_I and fills a plenum 43 (Figure 16C) defined outside of the potted ends of the gas exchange fibers 40 but inside of the housing (the housing 31 is cutaway on that side and the potting not illustrated to expose the fibers 40 in the blood/oxygen paths 10). Blood is provided from the inlet 18_I in the upper left of Figure 15 (which represents a port 18 or 18' of one of the inlet/outlet manifolds 16 or 16' described previously). Figure 16A is a cross sectional view of a blood/oxygen path 10 of the present invention to be installed in the housing 31 of Figure 15. The gas passes through the blood/oxygen path 10 in the direction C through the gas exchange fibers 40, while blood flows through gaps between the gas exchange fibers toward the outlet 18_O (in the lower right of the module as seen in Figure 15), which represents an inlet/outlet manifold 16 as previously described. Thus, blood travels downward and across the oxygenator 10. As noted above, various arrangements of gas exchange fibers 40 are available in the art, and the spacing between the fibers may be created by several means which ensure good blood flow with no stagnation.

The water to control the temperature of the blood in the oxygenator enters the housing through a port 28_I and exits through port 28_O. As with the gas, a water plenum 44 (Figure 16C) is defined between the housing 31 and the ends of each path on the side of the inlet 28_I. Of course, the ends of the blood/oxygen paths 10 on that side are potted closed, while the ends of the water paths 20 define

the openings 26, as seen in Figure 16B. As indicated by arrows A, water flows into the left side of the path 20 and out the right side through openings 26. Since the water path 20 has a flat and uniform surface, the water flows equally throughout the path without causing any heat concentration. The water is then collected and discharged from the oxygenator through port 28_O.

Figure 16C is a partial cross sectional view showing a sealing arrangement between the housing 31 and paths 10, 20 of the present invention. In this example, sealing is provided at each of the six corners of the housing 31. For example, air and fluid tight seals SEAL1 and SEAL2 are provided at both sides of the blood inlet/outlet 18 to isolate the blood path from the plenums 43 and 44. Further, air and fluid tight sealing S3 is provided at one corner of the housing 31 to isolate the water plenums 44 from the gas plenums 43.

<u>Plate-Type Modular Oxygenator Assembly</u>

Figures 17A-J are cross sectional views showing an exemplary process of forming a plate oxygenator similar to that of Figure 15 but with a modified gas exchange fiber arrangement. In Figure 17A, layers of gas exchange fibers are placed on each blood/oxygen substrate. Preferably, adjacent fiber layers or sheets are oriented with the fibers at different angles for enhanced blood flow and gas transfer. After each grouping of fibers, a substrate is positioned thereover, followed by a water path, another substrate, and another grouping of fibers, and so on. The blood inlet/outlet manifolds 16 are attached to the finished stack of substrates in Figure 17B. In Figure 17C (showing a water path 20), water inlet/outlet plugs 45 are provided. Figure 17D shows the ends of the gas exchange fibers optionally closed by a potting layer 46 before the main potting process. Figure 17E shows the assembly after the fiber end potting material is removed, and ready for the main potting steps. The stacked paths are placed in a potting housing 47 and the respective sides are bonded through the potting process of

Figure 17F and 17G. Then, the potting housing is removed as in Figure 17H. The ends of the bonded area of the fiber sides and the water sides are cut off in the process of Figure 17I. Finally, in Figure 17J, the stacked paths are then installed in the housing 31 having the inputs and outputs for the respective paths as previously described.

Potting Considerations For Plate-Type Modular Oxygenator

Figures 18A-18C are cross sectional views showing different degrees of potting depth around the blood inlet/outlet plenum 17' of the oxygenator. The view is directly through a layer of potting material and shows the duct 21' and adjacent substrate 35 in hidden lines. The potting depth of Figure 18A is correct and will sufficiently insulate each path from the other. A first potting side 50a terminates at an inner index rib 48 formed in the housing 31 and is juxtaposed against a second potting side 50b. The first and second potting sides 50a and 50b are desirably formed at separate times to produce planar interfaces as shown, but may also be formed simultaneously. The inner faces of the two sides 50a,b intersect at an apex 49 which is positioned inwardly from an outer edge of the adjacent substrates 35. This ensures that there is no void between the manifold and substrates, and prevents leaking at this location.

In contrast, Figure 18B shows a situation where the potting depth is insufficient. The inner face of first potting side 50a is above the index rib 48, thus relocating the apex 49 outward of the adjacent substrates 35. Therefore, a hole is established which may cause leakage between the paths.

Figure 18C shows a situation where the potting depth is excessive. The inner face of first potting side 50a is below the index rib 48 and within the boundary of the duct openings 19'. This may cause potting material to creep into the blood manifold, thus decreasing or otherwise disrupting the flow of blood therethrough.

Box-Type Modular Oxygenators

In the foregoing embodiments of the present invention, planar substrates are stacked in a manner shown in Figure 4 to form the paths of the oxygenator. As noted above, it is advantageous to use stainless steel as the oxygenator substrate since it has a high thermal conductivity to promote high efficiency heat exchange. Further, stainless is considered to be highly bio-compatible. However, stainless steel has disadvantages that it is expensive and heavy.

Planar Box-Type Modular Oxygenator

Figure 19A shows another example of modular oxygenator comprising a plurality of water path-defining boxes 120 made of a thermoplastic material such as polyester. The water boxes 120 are defined by outer walls 122 (with the top wall 125 removed in Figure 19A exposing an inner reinforcing strut 123). A blood/oxygen path will be formed between the outer surfaces of two adjacent water boxes 120. As described above, a number of water boxes 120 and blood/oxygen paths are alternately stacked together to meet the required size or capacity of the oxygenator. The reinforcement strut 123 helps prevent bowing of the top and bottom walls from internal or external pressures.

Figure 19B shows a top view of the water path-defining box 120 with the modified hexagonal shape of Figure 12. The water box 120 has rectangular shaped caps 127 at both ends used to form water inlet/outlet passages of the water path by cutting off the tips after the potting process. In this example, a plurality of spacers 121 mounted in receptacles on the top wall 125 of the water box 120 provide a gap between adjacent boxes for fiber placement and blood flow therethrough. In addition, a plurality of fiber guides 124 for positioning the gas exchange fibers 140 (Figures 21 and 23) are mounted in receptacles on the top wall 125. Although not shown, the receptacles for the spacers 121 and the fiber

guides 124 may also be provided on the bottom wall of the water box 120 projecting downward.

Figure 19C is a cross sectional view of the water box 120 showing the reinforcement strut 123 oriented in the longitudinal direction from end cap to end cap 127. As mentioned, the rectangular shaped caps 127 are closed at this stage. However, after potting all the paths stacked together, the end portions of the caps 127 are cut off to establish the water inlet/outlet openings. Figure 19D is a bottom plan view of the water box. Because the inner bottom surface of the water box 120 is flat and uniform, uniform water flows occur when the temperature controlled water is supplied thereto, and thus no heat concentration problem arises.

Figure 20 is a perspective view showing a manner of stacking the water boxes 120 of the present invention. Although not shown, between each two adjacent water boxes 120, a blood/oxygen path 110 (Figure 21) having a large number of gas exchange fibers 140 will be installed. Thus, the walls of the fibers 140 function as gas exchange mediums between their internal gas paths and the external blood path. As explained with reference to Figure 19A, spacers 121 determine the thickness of the blood/oxygen paths 110. Also provided between the water boxes 120 are the fiber guides 124 to position the gas exchange fibers 140 on the blood/oxygen paths 110. The spacers 121 and fiber guides 124 also function as mechanical supports for the stack of boxes.

<u>Assembly Of Planar Box-Type Modular Oxygenator</u>

Figures 21-23 are cross sectional views showing potting and assembling steps in producing the oxygenator of the present invention using the water path-defining boxes 120. Figure 21 shows a cross sectional view of the blood/oxygen path 110. The gas exchange fibers 140 are mounted on the upper surface of each water box 120 to form the blood/oxygen path 110. The gas exchange fibers 140

are positioned by the fiber guides 124 at an angle relative to parallel side walls 122 of the water box 120. Indeed, an exemplary method is to position sheets of fiber mat on the water paths, with the fibers in each sheet extending in parallel.

When the desired number of water boxes 120 are stacked together with blood/oxygen paths 110 therebetween, the stack of paths undergoes a potting process to establish isolation among the three paths, i.e., the water, blood, and gas paths. For example, as shown in Figure 21, the stack of paths is provided with potting materials such as polyurethane on four sides of the stack. As is well known in the art, such a potting process may be performed by a machine in which a device to be potted is rotated in a drum and potting materials are supplied to the drum to agglomerate on the inner face of the drum by centrifugal force.

In the example of Figure 21, both sides of the blood/oxygen paths 110 having the end portions of the gas exchange fibers 140 are formed of bonded areas BD1 and BD2 through the potting process. Similar to the example of Figure 5B, during the potting process, it is preferable to avoid exposing open gas exchange fiber ends to the potting materials so the potting material will not travel into the gas exchange fibers 140 by capillary action, for example. Thus, the ends of the fibers may be pre-potted. Further, in Figure 21, both right and left sides of the blood/oxygen paths 110 are also formed with bonded areas BD3 and BD4. Since the remaining sides of the module are not provided with the potting materials, the openings BL are created on the module to function as a blood inlet and a blood outlet while the thickness of the bonded areas BD1-BD4 is sufficient to isolate the blood path from the other paths.

Figure 22 is a cross sectional view through one of the water boxes 120 after potting. As noted above, the box like water box 120 is made of a thermoplastic material such as polyester or other similar expedient, and preferably has the reinforcement strut 123 in the longitudinal direction. After the foregoing potting process, the end portions of the caps 127 in the right and left sides are cut

off as shown in Figure 22 to establish a water inlet 126a and a water outlet 126b, respectively, on the water box 120. Also the end portions of the bonded areas BD1 and BD2 of the blood/oxygen path are cut off in a manner as shown in Figure 22 to expose open fiber ends and establish a gas inlet and a gas outlet, respectively.

Figure 23 is a cross sectional view through a blood/oxygen path 110 showing a situation where the stacked paths are installed in a housing 131 after the processes of Figure 21 and 22. Blood inlet/outlet manifolds 118 are fixed to the openings BL of the blood/oxygen path 110. The blood inlet/outlet manifolds 118 have a structure such as shown in Figures 8A or 8B to supply and receive blood for each layer of blood/oxygen path 110 of the oxygenator of the present invention.

Seals are provided at each corner of the housing 131 with respect to the stack of paths. The seals S11 isolate the plurality of blood paths from the water paths, seals S12 isolate the blood paths from the gas paths, and seals S13 isolate the water paths from the gas paths. The seals enable open communication between the plurality of water path openings 126 within the housing 131, and also enable communication between the plurality of fiber layers. Therefore, in the example of Figure 23, water path input/output 128, gas inlet/outlet 138, and blood inlet/outlet manifolds 118 are respectively created relative to the internal surface of the housing 131. In this manner, each of the paths is isolated from the others in the housing 131 and a single input and output line is sufficient to supply or receive respective fluids for each.

Recessed Box-Type Modular Oxygenator

Figure 24 shows another water path-defining box 220 of the present invention. As seen in Figure 24B, the water box 220 is formed, for example, of a base member 223 and a top wall 224. The base member 223 and the top wall 224 are bonded together in a manner shown in Figure 24A. As before, the box 220 is desirably molded of a thermoplastic material such as polyester, and has a hollow interior for passage of water. The water box 220 has rectangular shaped openings 227 at its longitudinal ends for establishing a water inlet and a water outlet.

Unlike the generally planar water box 120 of Figures 18-20, the hollow water box 220 has an upper recess 225A in a top wall and a bottom recess 225B in a bottom wall. The upper and bottom recesses 225 on adjacent boxes form a space for blood/oxygen paths wherein a large number of gas exchange fibers are positioned. Thus, the walls of the fibers function as gas exchange mediums between their internal gas paths and the external blood path. Preferably, as shown in Figure 24A, the side walls 222 of the recess 225 are shaped with two straight portions joining at an apex so as to function as a guide for positioning sheets of gas exchange fibers 240 in the recess 225, as will be described later.

Assembly Of Recessed Box-Type Modular Oxygenator

Figures 25A-25C are perspective views showing a process of mounting a plurality of sheets of gas exchange fibers 240 on the recess 225 of a first water box 220a. Preferably, the gas exchange fibers 240 are pre-fabricated in sheet like mats for ease of assembling the oxygenator with uniform gaps between the fibers. The process shown is relatively labor-intensive, and is shown primarily to illustrate the internal construction of the modular oxygenator. In practice, a more automated process would likely be developed and optimized base on these fundamental steps.

In Figure 25A, the first sheet of gas exchange fibers 240a is placed on the

recess 225 between the side wall portions 222A (with the parallel side wall portion not numbered). In Figure 25B, a second sheet of gas exchange fibers 240b is placed over the first sheet in the recess 225 between the other side wall portions 222b of the recess. Thus, the gas exchange fibers in the second sheet 240b are oriented in a direction different and oblique from that of the gas exchange fibers of the first sheet 240a. As shown in Figure 25C, the third sheet of gas exchange fibers 240c is placed over the second sheet 240b in the recess 225 between the side wall portions 222A. This process is repeated until an appropriate number of fiber sheets is stacked to form a blood/oxygen path 210. In this manner, the gas exchange fibers 240 of each layer are crossed over one another, which, for non-woven fiber mat, makes sufficient gaps between the fiber layers for the blood flowing therethrough. Therefore, if monofilaments are wound around individual gas exchange fibers 240 for spacing, they are desirably necessary only for the first and last layers of gas exchange fibers which directly contact the surfaces of the recesses 225.

In the next step, as shown in Figure 26, a second water box 220b is placed over the blood/oxygen path 210 so that the sheets of gas exchange fibers 240 placed on the upper recess 225A on the first water box 220a project and fill the lower recess of the upper water box 220b. Spaces 217 on opposed short sides of the six-sided shape defined by the water boxes are provided therebetween to form a blood inlet and a blood outlet to the region of the gas exchange fibers. Such spaces 217 may be produced by contacting portions of the boxes or spacers positioned between the first and second water boxes, as described with reference to Figures 18-20.

After stacking the desired number of paths, the stack as shown in Figure 27 undergoes a potting process by first inserting the stack in a potting housing 251. As will be described below, the number of paths may be varied to vary the volumetric capacity of the final oxygenator, for use with neonatal patients all the

way up to the largest adult. Prior to potting, however, the openings 227 are closed with caps 229 to prevent entry of the potting compound.

In Figure 28 the stack of paths has been inserted in the potting housing 251 (shown in hidden lines). As is well known in the art, in the potting process a potting material, such as polyurethane, is injected in the potting housing 251. A potting machine (not shown) may rotate the potting housing 251 and the stack of paths therein so that the potting material is concentrated on the inner walls of the housing 251 by a centrifugal force, and thus pots the outer surfaces of the stack.

In the example of Figure 29, the potting material is provided at the input and output sides of the water path as well as the input and output sides of the gas path. This step is substantially the same as the potting process shown in Figure 21. Thus, the bonded areas BD1, BD2, BD3 and BD4 with the thicknesses as shown are formed on the stack of paths.

In the next step, the subassembly of stacked and bonded path-defining boxes is taken out from the potting housing 251 and, as shown in Figure 30, each end portion of the bonded areas is cut off. This process is substantially the same as the potting process shown in Figure 22. As a consequence, inlet and outlet openings are created for each of the paths to allow the desired fluid or gas passing therethrough while establishing isolation from the other paths. Note that the caps 229 are cut off exposing inlet/outlets 228 for the water path. Likewise, inlet/outlets 218 for the blood path and the inlet/outlets 238 for the gas path are respectively created.

The subassembly of stacked and bonded path-defining boxes is then installed in an oxygenator housing 231 in the steps shown in Figures 31-33. (It will be noted that the dimensions of the subassembly seen in Figure 32 are larger than those of the subassembly of Figure 30; however, all other structure remains the same). In this example, as shown in Figure 31, a potting material layer (shown by the dashed line fluid level) is provided in the bottom of the

housing 231 before inserting the stack to seal the stack to the bottom floor of the housing as well as fixing it to the housing, as shown in Figure 32. Seals such as S1, S2 and S3 in Figure 23 are provided between the stack of paths and housing 231. Finally, a lid 233 is bonded to the housing 231 and tubular seals 234 are provided for the input and output ports as shown in Figure 33 to maintain sterility of the interior of the oxygenator.

Since the size of the oxygenator is desirably customized to the size of a particular patient, it is important that the size of the oxygenator can be flexibly adjusted without unduly increasing the cost. As mentioned above, the number of water and blood/oxygen paths within a particular housing 231 may be modified to vary the volumetric capacity of the oxygenator. To this end, a number of different sized housings may be provided to accommodate different numbers of paths, or unused space within a single "one-size-fits-all" housing may be filled with additional potting material, or with a stent. The only limitation to the latter approach is that the respective common plenums for the blood, gases and water be open to the input and output ports in the housing. The housing 231 may be dimensioned to contain a stack of paths resulting in a volumetric capacity of between 50 and 200 cc.

Variable Capacity Box-Type Oxygenators

As mentioned, the oxygenator assembled by the foregoing procedure may be internally customized to adjust the volumetric capacity of the overall oxygenator. Alternatively, a standard capacity housing 231 may be filled with path-defining members and used as a building module to provide varying capacity oxygenators. As shown in Figures 34A-34C, two or more oxygenator modules can be combined to increase the size of the overall oxygenator. For example, one module may be used for a neonatal oxygenator 252 as in Figure 33A, two modules may be used for a small adult oxygenator 254 as in Figure 34B, and three

modules may be used for a large adult oxygenator 256 as in Figure 34C. The input and output ports to these units 250 may be connected in parallel to common fluid lines (not shown), or may be otherwise more rigidly connected in series,

such as with couplers 260 (Figure 34A), as will be apparent to one of skill in the art.

Recessed Box-Type Modular Oxygenator With Fiber Spacing

Figure 35 shows another example of a water path-defining box 320 which is similar to the example of Figure 24A. Figure 35A shows the exterior of the water box 320 while Figure 35B shows the interior with a top wall removed. As with the earlier embodiment, the path-defining water boxes 320 are stacked together while blood/oxygen path-defining members are provided in the recesses therebetween

The outer shape of the water box 320 is different from that of the water box 220 of Figure 24A in that a plurality of bumps or ribs 330 are provided on the exterior surfaces of recesses 325A and 325B. The bumps 330 create gaps between the surfaces of the recesses 325 and the sheet fibers to allow blood flow therebetween, thus eliminating the need for a fiber layer wound by mono-filaments. Alternatively, grooves or other such indentations in the surfaces of the recesses 325 may provide the blood flow gaps. In this example, the bumps 330 in Figure 35A are formed in a manner of parallel lines, however, other types of surface arrangements, such as crossing lines or a large number of lumps, a plurality of parallel grooves and the like, are also feasible.

A reinforcement strut 323 is provided inside of the water box 320 as shown in Figure 35B. Preferably, the strut 323 is positioned in the center of the water box 320 in a longitudinal direction. The water box 320 is preferably made of a thermoplastic material such as polyester, and the planar panels may not be strong enough to withstand bowing from stresses imposed by internal or external fluid pressures. The reinforcement strut 323 may be arranged in a single line or in plural parallel lines. To further strengthen the water box 320, a plurality of ribs or bumps 332 also desirably molded on the interior surfaces of recesses 325A and

325B.

Box-Type Water Module Mold Process

An example of a mold process for producing the water box 320 of Figure 35 is shown in the perspective views of Figures 36A-36K, and in the corresponding plan views of Figures 37A-37J. A base mold 351 and side molds 352A and 352B are provided as shown in Figure 36A/37A. The side mold 352A has a slit 353A and the side mold 352B has a slit 353B to form the strut 323 about the center of the water box 320. The side molds 352A and 352B are linearly inserted in the base mold 351 as shown in Figures 36B/37B, 36C/37C, 36D/37D and 37E. When the side molds 352A and 352B are fully inserted in the base mold 351 in Figure 36D, a plurality of slits 357 are formed by the molds as best shown in Figure 37E to form a plurality of parallel struts 323 in the water box 320.

Then, a cover mold 355 is placed over the base mold 351 in Figure 36E. In Figure 36F/37F, when all the molds are in position, the plastic material is injected in the molds as is well known in the art. After passing a predetermined time, molds are taken apart as shown in Figures 36G-36I/37G-37I by linearly retracting the side molds 352A and 352B. The water box 320 having a plurality of parallel bumps 330 is produced on each of the recesses 325A and 325B under this process as shown in Figure 36I. In this example, the water box 320 has rectangular openings 326 at both ends as shown in Figure 36I. To undergo the potting process as described with reference to Figures 21-22 and Figures 27-30, the water box 320 is provided with caps 327 as shown in Figures 36J and 36K.

With reference to Figures 38 and 39, the water box 320 has side walls 322A and 322B to orient the sheet fibers 340. In the same manner shown in Figure 25, the gas exchange fibers 340 are placed over the recess 325A in parallel with the corresponding side walls 322A or 322B. Thus, each of the sheet fibers 340 is alternately placed over the other sheet fiber 340 in the different directions,

which facilitates the gas exchange rates because the blood flows through the gaps formed among the fibers without using mono-filaments around the gas exchange fibers 340. Further, in the bottom and top layers of the sheet fibers 340, since the bumps 330 establish gaps between the surface of the recesses 325 and the sheet fibers 340, the blood flows smoothly through the gaps without using the mono-filaments around the gas exchange fibers 340.

Modular Pipe Oxygenators

Figures 40-50 show another embodiment of the modular oxygenator of the present invention wherein pipe-like path-defining members are combined to form a modular oxygenator. In the earlier embodiments, plates or box structures were used to form paths and stacked linearly to define an oxygenator. In the modular pipe embodiment, a plurality of parallel, spaced pipes are grouped in a housing to form an oxygenator module. Blood may flow through the pipes or outside thereof, while water flows in the space not occupied by blood. Thus, a blood/oxygen path is defined either within each pipe, or outside of the pipes, and likewise, a water path is defined either within each pipe, or outside of the pipes. The walls of the pipes form direct conductive heat transfer mediums between the blood and water. Gas exchange fibers traverse the blood path, whether defined in or outside of the pipes. The pipes may be arranged within the housing in a number of ways, and are secured therein with potting material. The housing, pipes and potting material define plenums which are in fluid communication with the respective blood or water paths, or with open inlet end or outlet ends of the gas exchange fibers. The housing includes inlets and outlets in communication with the plenums for the three fluids.

The modules may function as stand alone oxygenators, but are desirably configured to connect together to form a multiple module oxygenator. The aggregation of modules may have their inlets and outlets connected in series so

that there is a single flow path through the oxygenator, although a diverging flow through parallel paths is a possibility. The pipes desirably have a hexagonal shape in cross section to enable close packing of a plurality of pipes with appropriate spacing therebetween. The desired hexagonal shape of the pipes has a further advantage of a large external surface area relative to volume. The material of the pipes may be stainless steel, polyurethane or the like, and may depend on the particular fluid flow in and around the pipes.

Figures 40-42 show basic flow arrangements of the modular pipe oxygenator of the present invention. In the examples of Figures 40-41, seven hexagonal pipes 400 are combined into an arrangement having a center pipe and six surrounding pipes to form an oxygenator module, although many other combinations are also feasible. Figure 42 shows an oxygenator module with only six circularly-arranged pipes 400, minus the center pipe.

In the example of Figure 40, gas exchange fibers 440 are installed and equally spaced within each pipe 400 so as to carry out the oxygenation of the blood within the pipes 400. The pipes 400 thus define blood paths therein, and blood flows longitudinally within the pipes 400 but outside of the fibers 440 to achieve gas diffusion through micro-pores of the fibers. Thus, the walls of each fiber functions as a gas exchange medium between the gas path and the blood path. In this arrangement, water flows outside and transversely between the pipes 400 to control the blood temperature within the pipes. The pipes 400 are therefore spaced in conventional ways to allow passage of water, and the spaces created thereby represent a single, connected water path. Of course, as will be understood, baffles may be used to divert the water flow and create separate flow paths.

In the embodiment of Figure 41, in contrast, the gas exchange fibers 440 are arranged outside of the pipes 400 and blood caused to flow between the spaced pipes and fibers to achieve gas diffusion. Water is introduced within the pipes

400 to control the blood temperature flowing outside of the pipes. The blood enters and exits in a transverse direction with respect to the length of the pipes 400 and the fibers 440. In this embodiment, the pipes 400 thus define water paths therein, while blood paths are created outside of the pipes. The pipes are shown as relatively large in comparison to the spaces therebetween, but may also comprise pipes which are sized comparable to the spaces therebetween.

The water and gas flow patterns of Figure 42 is the same as that of Figure 41, with the water paths within the pipes and the blood path outside of the pipes, however, the direction of blood flow is different. In Figure 42, the blood flows from surrounding areas radially toward the center of the circle of six circularly distributed pipes 400 and exits in a longitudinal direction in a channel at the center of the pipes.

Figure 43 shows an example of aligning the gas exchange fibers 440 outside of the pipes 400 in the arrangements of Figures 41 and 42. To efficiently pack the fibers 440 in the manner of Figure 43, a large number of fibers are formed in sheets or mats and positioned in parallel uniformly outside of the hexagonal pipes 400. Any number of packing arrangements are possible.

<u>Assembly Of Modular Pipe Oxygenators</u>

Figures 44A-F show steps in an exemplary a process for producing an oxygenator module having a plurality of pipes. Those of skill in the art will recognize that other assembly processes are available, and the present example should not be construed to limit the invention to any one sequence or technique.

Figure 44A shows a first step in which a hollow elongated pipe 450 has been placed in a spacer recess 454 of a bottom potting cap 452. The pipe 450 illustrated is hexagonal in cross-section, and the recess 454 is formed as a slightly larger hexagonal cup in a bottom wall of the potting cap 452. In addition, the potting cap 452 is hexagonal shaped with an upstanding rim 456. The module

being formed has the pipe arrangement and flow characteristics of Figure 40, with six pipes in a circle surrounding a center pipe, blood flowing through blood paths within the pipes, gas exchange fibers in the blood paths, and water flowing between the pipes. Consequently, the potting cap 452 includes seven recesses 454 for spacing the hexagonal pipes to accommodate water flow therebetween.

Figure 44B illustrates the seven pipes 450 positioned in the bottom potting cap 452 and an outer sleeve-like housing 458 in phantom surrounding the pipes. The housing 458 is desirably formed as a hexagonal tube and fits within the rim 456. Two panels 460 are shown in two adjacent lateral sides of the sleeve 458, the panels being scored on their peripheries, or otherwise constructed to enable removal from the sleeve, as will be described below. A top potting cap (not shown) identical to the bottom cap 452 is then positioned over the assembly of the pipes 450 and sleeve 458, with the top ends of the pipes being captured (and therefore spaced from one another) in downwardly facing recesses in the top cap. The recesses 454 also serve to close the opposite ends of the hollow pipes 450.

Potting material is then introduced to the assembly using conventional means in a manner to form two planar layers (a top layer 461 shown in Figure 44C) normal to the axes of the pipe and adjacent the top and bottom potting caps 452. Subsequently, the top and bottom potting caps 452, with the associated recesses 454 and pipe ends are severed to result in the oxygenator core 462 shown in Figure 44C. This core 462 defines blood paths 464 within the now anchored pipes 450 and a water path (not numbered) outside of the pipes and within the sleeve 458. The water path is sealed from the exterior of the sleeve 458 by the layers 461.

Figure 44D schematically illustrates the combination of the oxygenator core 462 with a plurality of gas exchange fibers 464 and a pair of blood plenum caps 466. The fibers 464 align longitudinally within each of the pipes 450 and have a length sufficient to extend well beyond the layers 461. The blood plenum

caps 466 each have an open end to receive the extended ends of the fibers 464, and which are secured to the top and bottom of the oxygenator core 462. The spacing of the fibers 464 within the pipes may be accomplished using downwardly facing recesses in the caps 466, similar to the recesses 454 for spacing the pipes 450. A potting procedure similar to that used to form the layers 461 is performed to isolate the ends of the fibers 464 from the blood plenum within the caps 466. That is, after the potting material has cured, the outermost ends of the assembly shown on the right in Figure 44D are severed to form flat layers of potting material with open fiber ends exposed in the pattern of the seven pipes 450. Two panels 468 are shown in two adjacent lateral sides of each blood plenum cap 466, the panels being scored on their peripheries, or otherwise constructed to enable removal from the cap, as will be described below.

Now with reference to Figure 44E, the assembly of Figure 44D has a top and bottom gas plenum caps 470 attached thereto. The caps 470 are hollow with open ends secured to the outermost ends of the blood plenum caps 466. This creates a gas plenum in fluid communication with the open ends of the cut fibers 464. The caps 470 are constructed in a similar manner as the blood plenum caps 466, and include removable panels 472 in at least two lateral sides.

Still with reference to Figures 44D and 44E, a number of the panels 460, 468, and 472 are removed depending on the particular module configuration desired, as will be clear below. For a solo module oxygenator 474, as seen in Figures 44D and 44F, two each of the panels 460, 468, and 472 are removed to form windows into interior spaces in the oxygenator. Specifically, two windows 476a and 476b are formed by removing panels 460 from two adjacent lateral sides of the sleeve 458, two windows 478a and 478b are formed by removing one panel each from the top and bottom blood plenum caps 466, and two windows 480a and 480b are formed by removing one panel each from the top and bottom gas plenum caps 470. Note that the windows 476a, 478a, and 480a are commonly located on

a lateral side of the oxygenator 474, while the windows 476b, 478b, and 480b are commonly located on an adjacent lateral side. This permits the addition of two inlet/outlet plates 482a and 482b to the adjacent lateral sides to provide an interface with external fluid conduits. Each plate 482a,b includes a water inlet/outlet 484, a blood inlet/outlet 486, and a gas inlet/outlet 488 (denoted with the appropriate suffix a or b). The location of the inlet/outlets 484, 486, 488 on the plates 482a,b ensures fluid communication through one of the windows 476, 478, 480. That is, for example, the upper gas inlet/outlet 480b communicates with the window 480b formed in the upper gas plenum cap 470. In addition, although the inlet/outlets are shown attached to a common plate, each may be assembled to the respective windows separately. The assembled oxygenator 474 is seen in Figure 44F and can be connected with appropriate fluid supply and discharge conduits.

Those of skill in the art will recognize the various paths of the respective fluids through the oxygenator 474 afforded by the interface with the plates 482a,b. Thus for example, gas flows from the inlet/outlet 488a through the window 480a into the lower gas plenum 470, from there into the open inlet ends of the hollow gas exchange fibers, through the fibers, out of the open outlet ends of the fibers into the upper gas plenum 470, through the window 480b and out of the oxygenator 474 via the inlet/outlet 488b. The bottom to top flow can be reversed, of course. Likewise, the blood and water flows are similar with the blood passing within the internal hexagonal pipes and the water flowing therearound. Variations on the flow directions are possible, although the blood desirably flows from top to bottom to obtain the benefit of its fluid potential energy (and reduce the fluid pump energy needed to circulate the blood).

Single Or Multiple Modular Pipe Oxygenators

The oxygenator 474 seen in Figure 44F is constructed with inlet/outlets on

two adjacent lateral sides to function as a stand alone oxygenator. The present invention, as embodied in the aforedescribed modular pipe oxygenator 474, is especially well suited for combining stand alone oxygenators into a larger aggregate oxygenator. For example, Figures 45A and 45B show two oxygenators 490a and 490b, each identical to the oxygenator 474, connected at facing lateral sides along a straight line to form a two module oxygenator 492. Some of the windows, previously described, in the facing sides will be in fluid communication. The cross-section is taken through the oxygenator core to show hexagonal blood-carrying pipes 494 separated to form paths for the heat exchange water. A water inlet window 496a is positioned on the left side of the left module oxygenator 490a, and a water outlet window 496b is positioned on the right side. A water inlet window 498a is positioned on the left side of the right module oxygenator 490b, and a water outlet window 498b is positioned on the right side. The inlets are denoted with a plus (+) sign and the outlets with a minus (-). Thus, water flows from left to right from the water inlet window 496a to the water outlet window 498b and between the hexagonal blood-carrying pipes 494 of both module oxygenators 490a,b. The blood and gas paths similarly travel through both modules, with the flow direction being downward through one and upward through the other, because of the communicating windows. In this fashion, the gas and heat exchange capacity of the oxygenator 492 is double that of the solo oxygenator 474.

Figures 46A and 46B illustrate another multi-module oxygenator 500 which combines three of the oxygenators 474. In this configuration, none of the modules interface in a straight line, so the water path travels a winding path, indicated generally by the line 502. This flow path 502 is made more circuitous through each of the modules by the imposition of baffles 504. Each baffle 504 is a bent plate which extends generally inwardly from a corner of the hexagonal module cross-section and between the inlet and outlet windows. Desirably, each

baffle 504 is formed to fill the narrow spaces between adjacent hexagonal pipes, so that there are no nooks and crannies created thereby. A baffle such as that shown at 504 is also desirably used for the solo oxygenator 474 seen in Figure 44F, at least where the inlets and outlets are located on adjacent lateral sides of the module. The baffles 504 encourage a sweeping flow of water, or blood if configured differently, through the connected modules, thus helping to promote uniform heat exchange throughout each module cross-section.

Note finally the positions of the respective blood and gas inlet/outlets. Because there is an odd number of modules in the oxygenator 500, the blood enters an upper inlet 506a and exits a lower outlet 506b, while the gas enters a lower inlet 508a and exits an upper outlet 508b. As mentioned previously, the flow of the blood and gas continues longitudinally through each module and thus must enter and exit at opposite ends. An even number of modules, such as in the oxygenator 492 of Figures 45A and 45B, dictates that the inlet and outlet of the blood will be at the same elevation, and similarly for the gas. For fluid head reasons, therefore, an odd number of modules is preferred so to take advantage of the fluid potential energy of the blood.

Parallelogram Modular Pipe Oxygenators

Figures 47A and 47B are examples of oxygenators illustrating the limitless configurations that each module may take. The stand alone modular oxygenator 510 shown has a horizontal cross-sectional shape of a parallelogram, with two longer opposed parallel sides forming water inlets and outlets, as shown. That is, a water inlet manifold 512a and a water outlet manifold 512b attached to open windows formed on a central housing 514. The manifolds 512a,b are shown exploded in Figure 47A, and assembled in Figure 47B. The oxygenator 510 is constructed in a similar manner as the hexagonal oxygenator 474, with upper and lower gas and blood manifolds (not shown). Blood preferably travels vertically

through each of a plurality of hexagonal pipes 516 and gas travels through a plurality of hollow fibers 518 within the pipes. The blood and gas inlet/outlets are not shown, but are desirably positioned above and blow the central water path shown. The pipes 516 are spaced to allow water flow therebetween, in this case from left to right. The hexagonal pipes 516 are cascaded in a natural side-to-side juxtaposition to form the parallelogram cross-section.

Figures 48A and 48B illustrate multiple parallelogram oxygenator modules 510 connected in series to form aggregate and increased capacity oxygenators. The connection can be in a linear progression, as in the two module design of Figure 48A, or in a staggered progression, as in the three module design of Figure 48B. In each case, blood, water, and gas flow through the entire assembly in series paths. Note the stepped male and female configurations of the opposed open ends of each intermediate housing. This arrangement facilitates connection between housings and between the terminal housings and water manifolds.

Selection Of A Modular Oxygenator

The present invention facilitates selection and production of various sized oxygenators based on various medical parameters. Such parameters include, for example, the patient's size, age, condition, and blood chemistry. The oxygenator selection may also depend on the surgical procedure being done and on surgeon preference. In short, a number of factors are taken into account when selecting an oxygenator, and the optimum sized oxygenator ranged across a continuum.

Those of skill in the art will recognize that a much larger assortment of oxygenators can be more easily be made available with the various designs and construction techniques described herein. For example, the housing 30 of the solo module oxygenator in Figure 1A can accommodate any number of stacked substrates to form from one to ten or twenty pairs of blood/oxygen and water

paths. Similarly, the oxygenators shown in Figures 34A-C are constructed with one, two or three modules in series, or with progressively larger outer housings enclosing a correspondingly greater number of blood and water path-defining stacked boxes. Likewise the modular oxygenator 474 of Figure 44F can function alone, or may be combined to form the oxygenators 492 and 500 of Figures 45 and 46. With the various constructions disclosed herein, therefore, the manufacturing assembly process is facilitated with standard modules.

It is understood that the examples and embodiments described herein and shown in the drawings represent only the presently preferred embodiments of the invention, and are not intended to exhaustively describe in detail all possible embodiments in which the invention may take physical form. Indeed, various modifications and additions may be made to such embodiments without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An integrated fluid oxygenator, comprising:

a plurality of independently functional oxygenator modules operatively attached together, each module having an outer housing with a fluid inlet port and a fluid outlet port, a gas inlet port and a gas outlet port, and a water inlet port and a water outlet port, the modules each including internal flow paths to facilitate oxygenation and heat regulation of the fluid, wherein the internal flow paths of the fluid, water, and gas for each module are in flow communication.

2. The oxygenator of Claim 1, wherein each independently functional module comprises:

a subassembly defined by a plurality of fluid impermeable heat transfer walls each having a water contact side and a fluid contact side, wherein some of the heat transfer walls each at least partially defines a fluid path on the fluid contact side and a water path on the water contact side, wherein the fluid paths and the water paths are sealed from each other, the subassembly further including a plurality of gas paths at least partially defined by semi-permeable gas exchange membranes in contact with fluid in each of the fluid paths, each gas path having an open inlet end and an open outlet end both of which are sealed from the fluid paths and the water paths;

a fluid inlet plenum in flow communication with the fluid inlet and the fluid paths;

a fluid outlet plenum in flow communication with the fluid outlet and the fluid paths, the fluid inlet and outlet plenums being positioned with respect to each fluid path to direct fluid flow therethrough when fluid is introduced to the fluid inlet;

a water inlet plenum in flow communication with the water inlet and the water paths;

a water outlet plenum in flow communication with the water outlet and the water paths, the water inlet and outlet plenums being positioned with respect to each water path to direct water flow therethrough when water is introduced to the water inlet;

a gas inlet plenum in flow communication with the gas inlet and the inlet ends of the gas paths; and

a gas outlet plenum in flow communication with the gas outlet and the outlet ends of the gas paths.

3. The oxygenator of Claim 2, wherein the heat transfer walls comprise parallel planar portions of a series of spaced substrates each forming seals with the housing to separate alternating fluid and water paths.

4. The oxygenator of Claim 3, wherein the housing has a hexagonal cross-section taken in the plane of the substrate planar portions with three pairs of opposed sides, and wherein each pair of inlet and outlet plenums for the fluid, water, and gas paths are associated, respectively, with one of the pairs of opposed sides.

5. The oxygenator of Claim 3, wherein the housing has a box shape, and wherein the substrates are arrayed within the housing and a potting compound provides sealed inter-connections between the substrates and housing and between adjacent substrates, the plenums being defined between the substrates and the housing partly by the inter-connecting potting compound.

6. The oxygenator of Claim 2, wherein the heat transfer walls comprise opposed panels of a plurality of box structures, the oxygenator including a stack of spaced box structures, wherein the water contacting sides of the heat transfer walls are defined by the internal surfaces of the opposed panels and the fluid contacting sides of the heat transfer walls are defined by the external surfaces of the opposed panels.

7. The oxygenator of Claim 6, further including spacers provided between the box structures to form gaps defining the fluid paths, wherein the gas paths are defined within hollow gas exchange fibers extending through each fluid path.

8. The oxygenator of Claim 2, wherein the heat transfer walls comprise walls of elongated pipes, the pipes being spaced apart within the housing.

9. The oxygenator of Claim 8, wherein the fluid paths are defined within each pipe, and the water paths are defined by the spaces formed between the pipes.

10. The oxygenator of Claim 8, wherein the water paths are defined within each pipe, and the fluid paths are defined by the spaces formed between the pipes.

11. The oxygenator of Claim 1, wherein the independently functional oxygenator modules connect to each other at juxtaposed straight sides, the inlets and outlets for each of the fluid, water, and gas flow paths are connected in series external to the housings.

12. The oxygenator of Claim 1, wherein the independently functional oxygenator modules connect to each other at juxtaposed straight sides, the inlets and outlets for each of the fluid, water, and gas flow paths are connected in series through openings in the juxtaposed straight sides.

13. The oxygenator of Claim 12, wherein the independently functional oxygenator modules have elongated hexagonal exteriors, with six straight sides including break-out panels in at least two for forming the openings.

14. The oxygenator of Claim 13, wherein there are an odd number of modules connected in a triangular arrangement with the fluid inlet to the first of the modules in series being elevated above the fluid outlet to the last of the modules.

15. The oxygenator of Claim 1, wherein the independently functional oxygenator modules are generally parallelepiped in exterior shape and are stacked vertically and connected to each other at juxtaposed horizontal sides.

16. The oxygenator of Claim 15, wherein the fluid inlets and outlets are cooperatively connected so that the fluid flow is in series downward through the modules.

17. A fluid oxygenator including one or more modules, each module comprising:

a subassembly defined by a plurality of fluid impermeable heat transfer walls each having a water contact side and a fluid contact side, wherein some of the heat transfer walls each at least partially defines a fluid path on the fluid contact side and a water path on the water contact side, wherein the fluid paths and the water paths are sealed from each other, the subassembly further including a plurality of gas paths at least partially defined by semi-permeable gas exchange membranes in contact with fluid in each of the fluid paths, each gas path having an open inlet end and an open outlet end both of which are sealed from the fluid paths and the water paths;

an outer housing enclosing the subassembly and having a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and

a gas outlet;

a fluid inlet plenum in flow communication with the fluid inlet and the fluid paths;

a fluid outlet plenum in flow communication with the fluid outlet and the fluid paths, the fluid inlet and outlet plenums being positioned with respect to each fluid path to direct fluid flow therethrough when fluid is introduced to the fluid inlet;

a water inlet plenum in flow communication with the water inlet and the water paths;

a water outlet plenum in flow communication with the water outlet and the water paths, the water inlet and outlet plenums being positioned with respect to each water path to direct water flow therethrough when water is introduced to the water inlet;

a gas inlet plenum in flow communication with the gas inlet and the inlet ends of the gas paths; and

a gas outlet plenum in flow communication with the gas outlet and the outlet ends of the gas paths;

wherein each module may independently function as a standalone oxygenator, or two or more modules may be positioned adjacent one another to function together as a multiple-module oxygenator with the fluid outlet of one connected to the fluid inlet of the other to provide a series flow of fluid through the modules.

18. The fluid oxygenator of Claim 17, wherein the heat transfer walls comprise parallel planar portions of a series of spaced substrates each forming seals with the housing to separate alternating fluid and water paths.

19. The fluid oxygenator of Claim 18, wherein at least one pair of inlet and outlet for the fluid, water, or gas paths is located on opposed sides of

the housing so that the corresponding flow of fluid, water, or gas is substantially in one direction.

20. The fluid oxygenator of Claim 18, wherein the housing has a hexagonal cross-section taken in the plane of the substrate planar portions with three pairs of opposed sides, and wherein each pair of inlet and outlet plenums for the fluid, water, and gas paths are associated, respectively, with one of the pairs of opposed sides.

21. The fluid oxygenator of Claim 20, wherein the fluid plenums each include elongate manifolds integrally formed with a series of ducts extending perpendicularly from the manifold and between adjacent substrates, the ducts providing flow paths between the manifold and the fluid paths.

22. The fluid oxygenator of Claim 20, wherein the hexagonal cross-section is irregular with one pair of opposed sides being substantially longer than the other two pairs of opposed sides to define an elongated rectangular mid-section with triangular end sections, each end section having a base coincident with one end of the rectangular mid-section and an apex outward therefrom.

23. The fluid oxygenator of Claim 22, wherein the substrates are sized with the parallel planar portions equal to the housing rectangular mid-sections, each substrate having triangular end sections size to fit within the triangular end section of the housing.

24. The fluid oxygenator of Claim 23, wherein the triangular end sections of both the housing and substrates converge in a direction normal to the planar portions of the substrates to minimize fluid prime volume required in these regions.

25. The fluid oxygenator of Claim 18, wherein the housing has a box shape, and wherein the substrates are arrayed within the housing and a potting compound provides sealed inter-connections between the substrates and housing

and between adjacent substrates, the plenums being defined between the substrates and the housing partly by the inter-connecting potting compound.

26. The fluid oxygenator of Claim 25, wherein the fluid plenums are each formed by an elongate manifold member interposed between the substrates and the housing and having openings connecting the several fluid paths.

27. The fluid oxygenator of Claim 25, wherein the gas paths are defined by a plurality of gas exchange fibers extending through each fluid path, the fibers being sealed with potting compound between the adjacent substrates defining each fluid paths and having open ends in communication with the gas plenums formed outside of the potting compound.

28. The fluid oxygenator of Claim 17, wherein the heat transfer walls comprise opposed panels of a plurality of box structures, the oxygenator including a stack of spaced box structures, wherein the water contacting sides of the heat transfer walls are defined by the internal surfaces of the opposed panels and the fluid contacting sides of the heat transfer walls are defined by the external surfaces of the opposed panels.

29. The fluid oxygenator of Claim 28, wherein each box structure is elongated with opposed ends defining openings in communication with the water plenums.

30. The fluid oxygenator of Claim 29, wherein each box structure further includes an internal strut extending generally between the end openings and in contact with the opposed panels to provide structural support thereto.

31. The fluid oxygenator of Claim 30, wherein each box structure comprises a two-part molded assembly with a base portion and a lid portion, and the internal strut is integrally molded with one of the parts.

32. The fluid oxygenator of Claim 29, further including spacers provided between the box structures to form gaps defining the fluid paths,

wherein the gas paths are defined within hollow gas exchange fibers extending through each fluid path.

33. The fluid oxygenator of Claim 32, wherein the gas exchange fibers are sealed within the fluid path by potting compound between adjacent box structures and have open ends in communication with the gas plenums formed outside of the potting compound.

34. The fluid oxygenator of Claim 33, wherein the fluid plenums each include elongate manifolds integrally formed with a series of ducts extending perpendicularly from the manifold and between adjacent box structures, the ducts providing flow paths between the manifold and the fluid paths.

35. The fluid oxygenator of Claim 28, wherein each box structure is generally flattened with the opposed panels being relatively large and spaced close together in comparison to the size of and spacing between the edges of the box structure, and wherein the edges comprise three pairs of parallel edges each pair having a common normal direction defining generally the direction of one of the fluid, water, or gas paths, with the water openings being formed in one pair of edges.

36. The fluid oxygenator of Claim 28, further including recesses formed in the opposed panels of the box structures, the gas exchange fibers being positioned within the recesses.

37. The fluid oxygenator of Claim 17, wherein the heat transfer walls comprise walls of elongated pipes, the pipes being spaced apart within the housing.

38. The fluid oxygenator of Claim 37, wherein the fluid paths are defined within each pipe, and the water paths are defined by the spaces formed between the pipes.

39. The fluid oxygenator of Claim 38, wherein the gas paths are defined within hollow gas exchange fibers positioned longitudinally within each pipe.

40. The fluid oxygenator of Claim 37, wherein the water paths are defined within each pipe, and the fluid paths are defined by the spaces formed between the pipes.

41. The fluid oxygenator of Claim 40, wherein the gas paths are defined within hollow gas exchange fibers positioned within the spaces formed between the pipes.

42. The fluid oxygenator of Claim 37, wherein the pipes have a hexagonal lateral cross-section.

43. The fluid oxygenator of Claim 42, wherein the pipes are arranged within the housing in hexagonal patterns so that the spaces therebetween are consistent and rectilinear.

44. The fluid oxygenator of Claim 43, wherein the pipes are close-packed within the housing, each pipe other than those adjacent the housing being shared by six hexagons.

45. The fluid oxygenator of Claim 43, wherein the pipes are arranged in overlapping hexagons surrounding a central space with no pipe, each pipe other than those adjacent the housing being shared by three adjacent hexagons.

46. A fluid oxygenator manufacturing kit comprising:

a subassembly defined by a plurality of fluid impermeable heat transfer walls each having a water contact side and a fluid contact side, wherein some of the heat transfer walls each at least partially defines a fluid path on the fluid contact side and a water path on the water contact side, wherein the fluid paths and the water paths are sealed from each other, the subassembly further including a plurality of gas paths at least partially defined by semi-permeable gas exchange membranes in contact

with fluid in each of the fluid paths, each gas path having an open inlet end and an open outlet end both of which are sealed from the fluid paths and the water paths;

a first outer housing adapted to enclose the subassembly when there are a first number of fluid and water paths defined therein, the first outer housing having a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and a gas outlet; and

a second outer housing adapted to enclose the subassembly when there are a second number of fluid and water paths defined therein greater than the first number, the second outer housing having a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and a gas outlet;

wherein an oxygenator may be assembled from the kit by combining the subassembly with either the first housing or the second housing, and wherein the following are defined by the assembled oxygenator:

a fluid inlet plenum in flow communication with the fluid inlet and the fluid paths;

a fluid outlet plenum in flow communication with the fluid outlet and the fluid paths, the fluid inlet and outlet plenums being positioned with respect to each fluid path to direct fluid flow therethrough when fluid is introduced to the fluid inlet;

a water inlet plenum in flow communication with the water inlet and the water paths;

a water outlet plenum in flow communication with the water outlet and the water paths, the water inlet and outlet plenums being positioned with respect to each water path to direct water flow therethrough when water is introduced to the

water inlet;

a gas inlet plenum in flow communication with the gas inlet and the inlet ends of the gas paths; and

a gas outlet plenum in flow communication with the gas outlet and the outlet ends of the gas paths.

47. A fluid oxygenator having two modules coupled together, each module being independently functional as an oxygenator and comprising:

an outer housing having a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and a gas outlet;

a plurality of fluid impermeable heat transfer walls within the housing each having a water contact side and a fluid contact side, wherein some of the heat transfer walls each at least partially defines a fluid path on the fluid contact side and a water path on the water contact side;

means for sealing the fluid paths and the water paths from each other

a plurality of semi-permeable gas exchange membranes having one side in contact with fluid in each of the fluid paths and defining gas paths on the opposite side, each gas path having an open inlet end and an open outlet end both sealed from the fluid paths and the water paths;

fluid plenum means for providing flow communication between the fluid inlet and the fluid paths, and between the fluid paths and the fluid outlet, the fluid plenum means being positioned with respect to each fluid path to direct fluid therethrough when fluid is introduced to the fluid inlet;

water plenum means for providing flow communication between the water inlet and the water paths, and between the water paths and the water outlet, the water plenum means being positioned with

respect to each water path to direct water therethrough when water is introduced to the water inlet; and

gas plenum means for providing flow communication between the gas inlet and the inlet ends of the gas paths, and between the gas paths and the outlet ends of the gas paths, the gas plenum means being positioned with respect to each gas path to direct gas therethrough when gas is introduced to the gas inlet;

wherein the two modules are coupled to function together with the fluid outlet of one connected to the fluid inlet of the other to provide a series flow of fluid through the two modules.

48. A method of selecting a fluid oxygenator, comprising:

determining approximate desired flow characteristics of the oxygenator based on patient parameters;

selecting an oxygenator based on the determined flow characteristics from an inventory of modules, wherein each module has approximate predetermined flow characteristics and comprises:

an outer housing having a fluid inlet and a fluid outlet, a water inlet and a water outlet, and a gas inlet and a gas outlet;

a plurality of fluid impermeable heat transfer walls within the housing each having a water contact side and a fluid contact side, wherein some of the heat transfer walls each at least partially defines a fluid path on the fluid contact side and a water path on the water contact side;

means for sealing the fluid paths and the water paths from each other

a plurality of semi-permeable gas exchange membranes having one side in contact with fluid in each of the fluid paths and defining gas paths on the opposite side, each gas path having an

open inlet end and an open outlet end both sealed from the fluid paths and the water paths;

fluid plenum means for providing flow communication between the fluid inlet and the fluid paths, and between the fluid paths and the fluid outlet, the fluid plenum means being positioned with respect to each fluid path to direct fluid therethrough when fluid is introduced to the fluid inlet;

water plenum means for providing flow communication between the water inlet and the water paths, and between the water paths and the water outlet, the water plenum means being positioned with respect to each water path to direct water therethrough when water is introduced to the water inlet; and

gas plenum means for providing flow communication between the gas inlet and the inlet ends of the gas paths, and between the gas paths and the outlet ends of the gas paths, the gas plenum means being positioned with respect to each gas path to direct gas therethrough when gas is introduced to the gas inlet;

wherein the selected modular oxygenator includes one or more modules, each module adapted to independently function as an oxygenator, or to operatively attach to another module and function together as an oxygenator with the fluid outlet of one connected to the fluid inlet of the other to provide a series flow of fluid through the two modules.

FIG. 1A

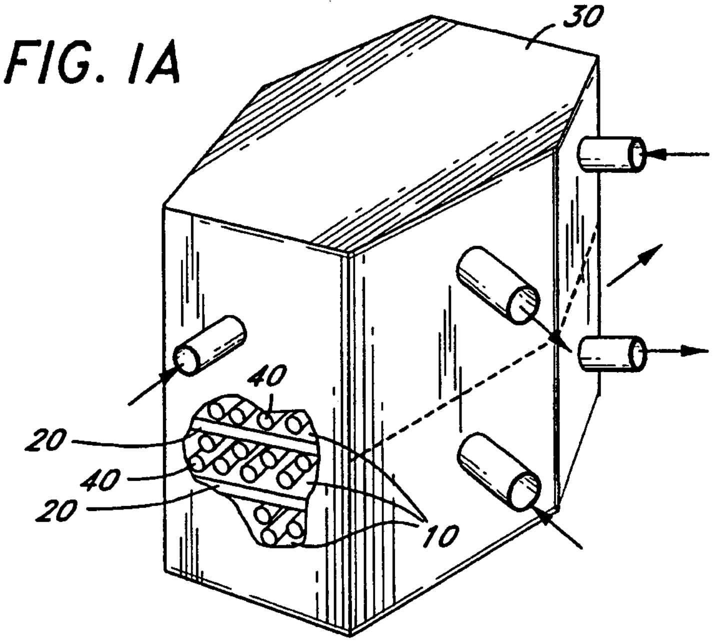


FIG. 1B

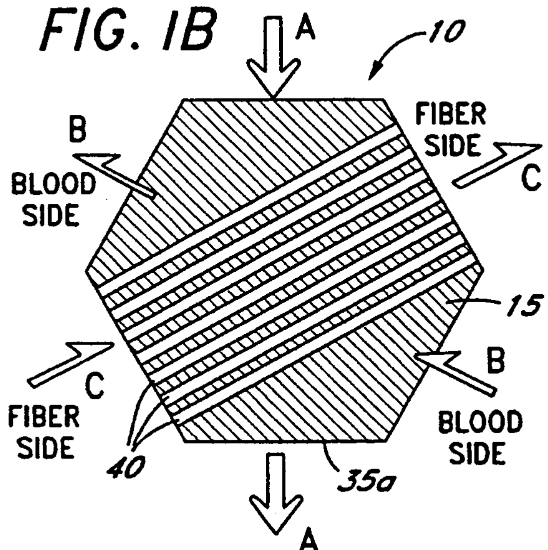


FIG. 1C

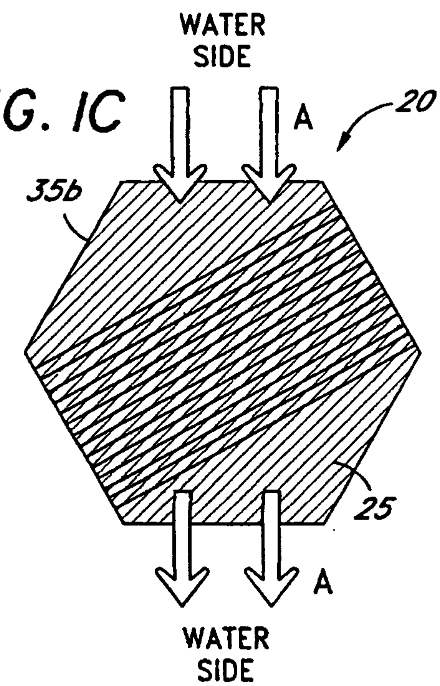


FIG. 2

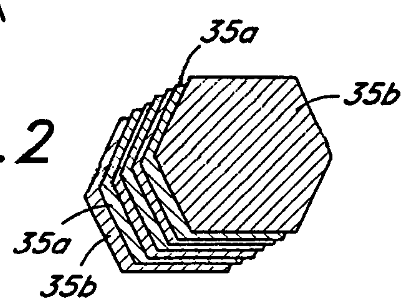


FIG. 3A

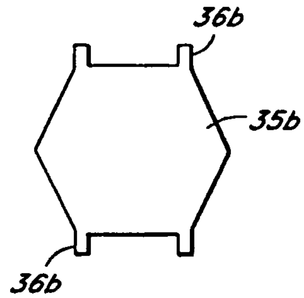


FIG. 3C

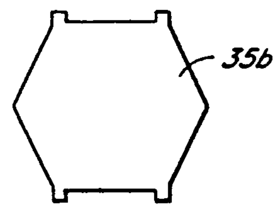


FIG. 3D

FIG. 3B

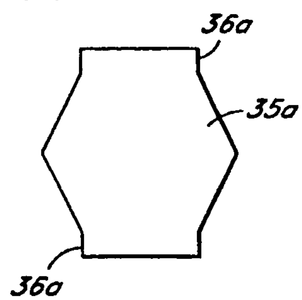


FIG. 3E

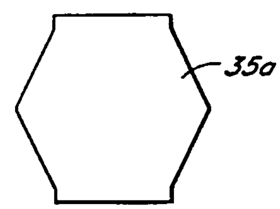
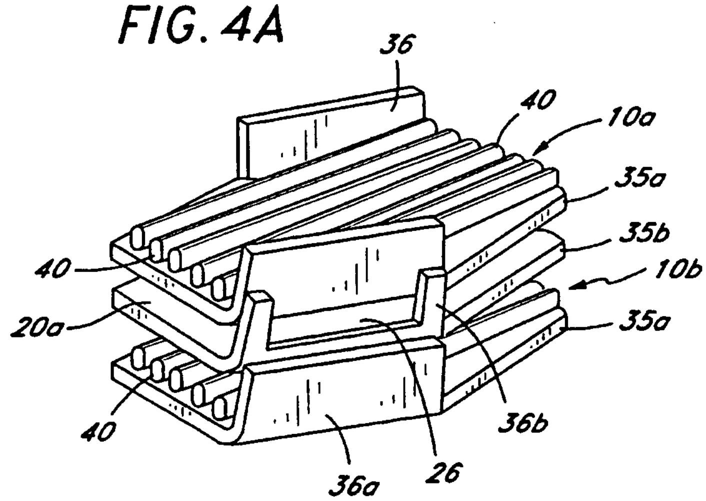


FIG. 3F

FIG. 4A


36
40
10a
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35b
40
10b
20a
35a
40
36b
26
36a

FIG. 4B

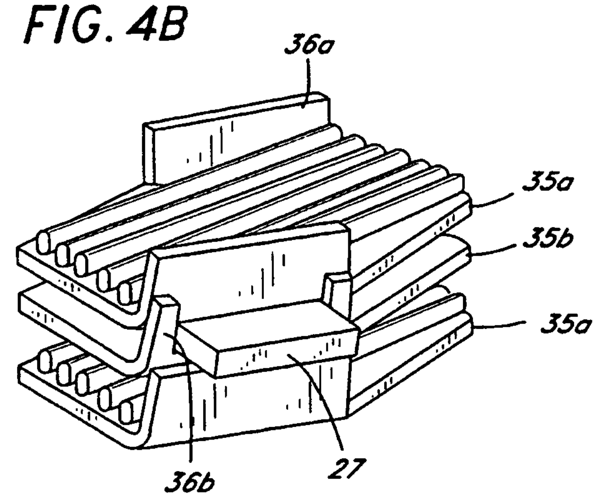

36a
35a
35b
35a
36b
27

FIG. 5A

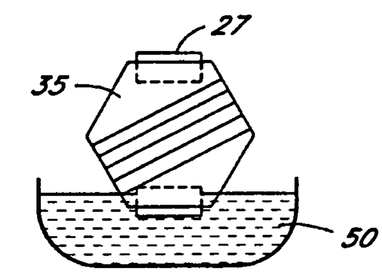


FIG. 5B

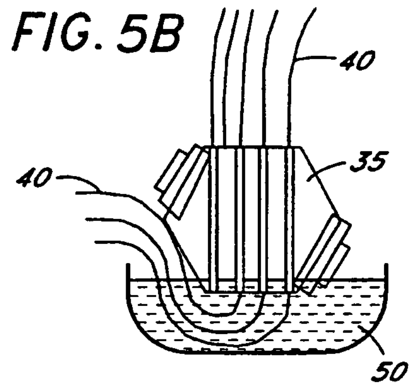


FIG. 6

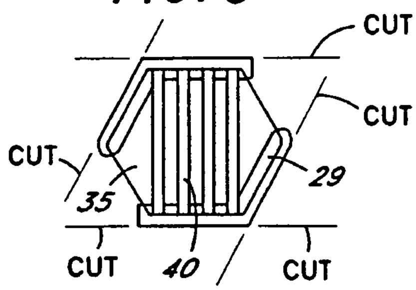


FIG. 7

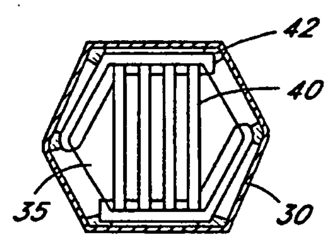


FIG. 8A

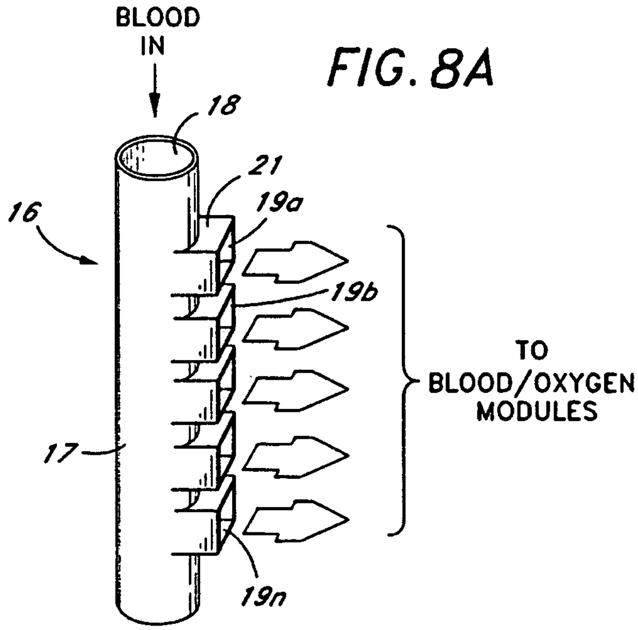

BLOOD
IN
18
21
19a
16
19b
TO
BLOOD/OXYGEN
MODULES
17
19n

FIG. 8B

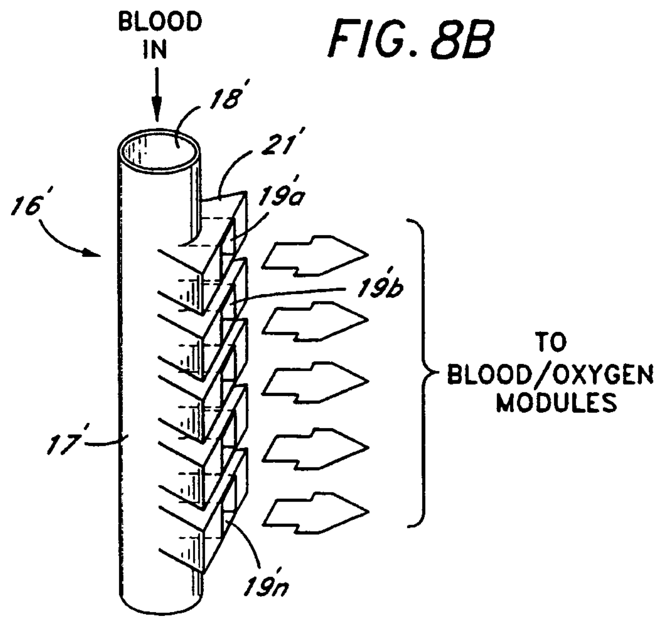

BLOOD
IN
18'
21'
19'a
16'
19'b
TO
BLOOD/OXYGEN
MODULES
17'
19'n

FIG. 9A

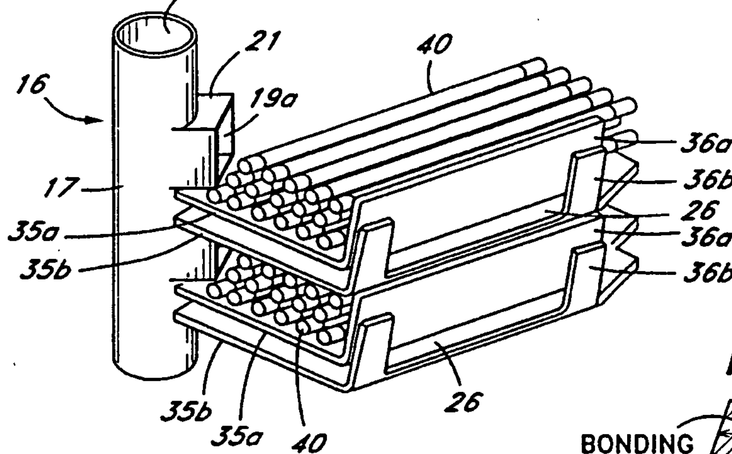


FIG. 9B

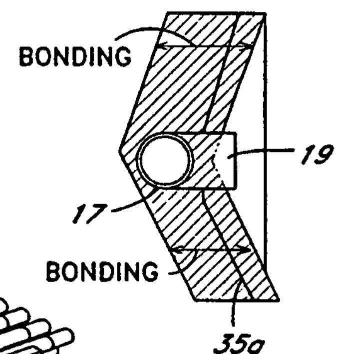


FIG. 9C

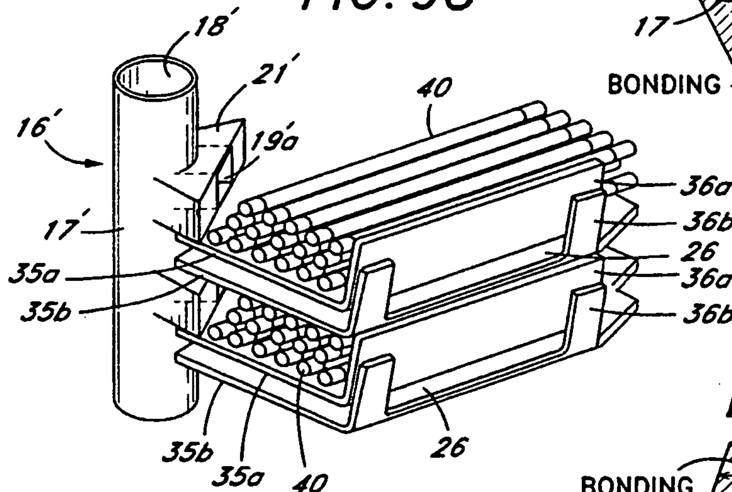


FIG. 9D

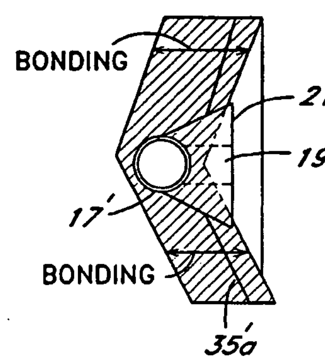


FIG. 10A

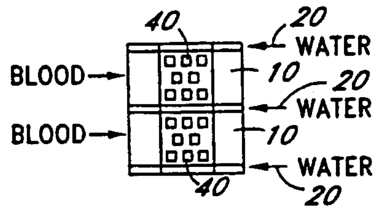


FIG. 10B

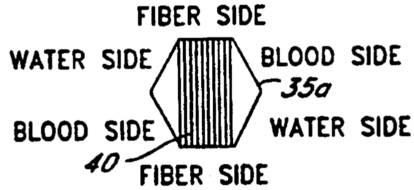


FIG. 11A

FIG. 11B

FIG. 11C

FIG. 12A

FIG. 12B

FIG. 13

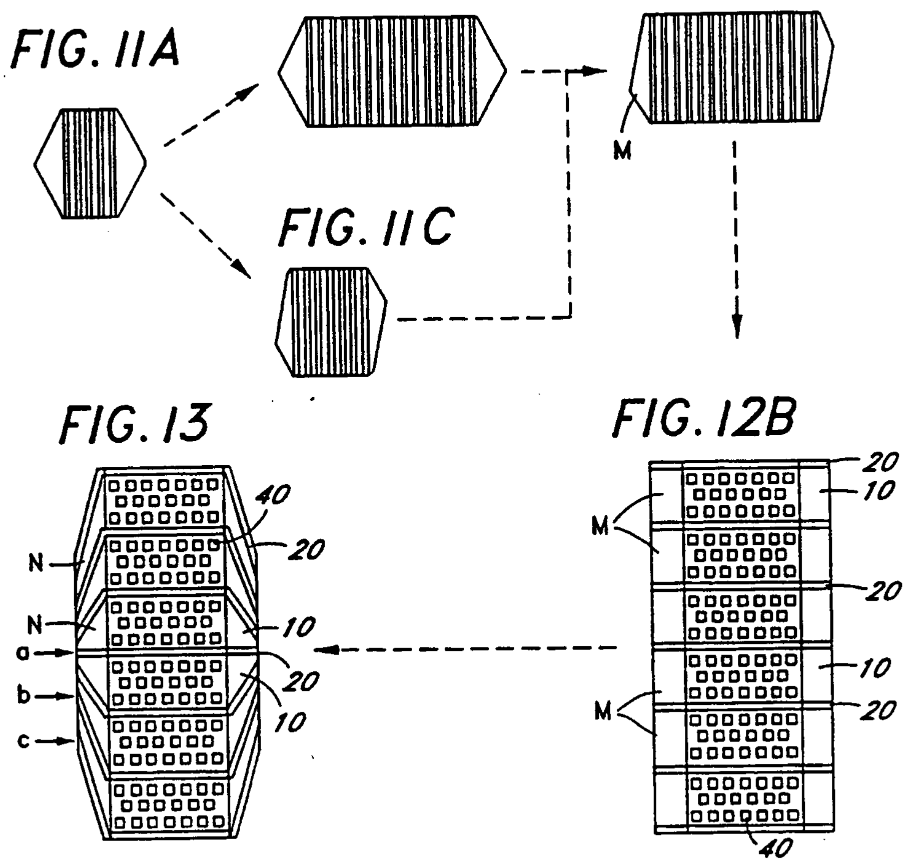


FIG. 14A

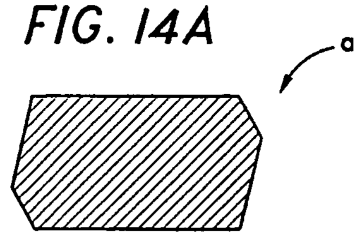


FIG. 14B

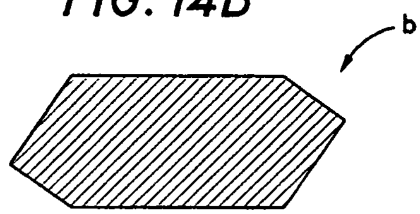


FIG. 14C

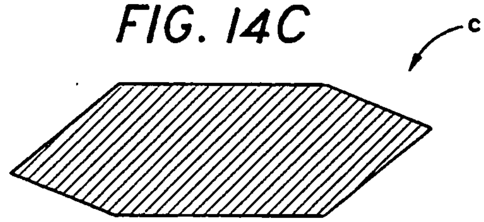


FIG. 15

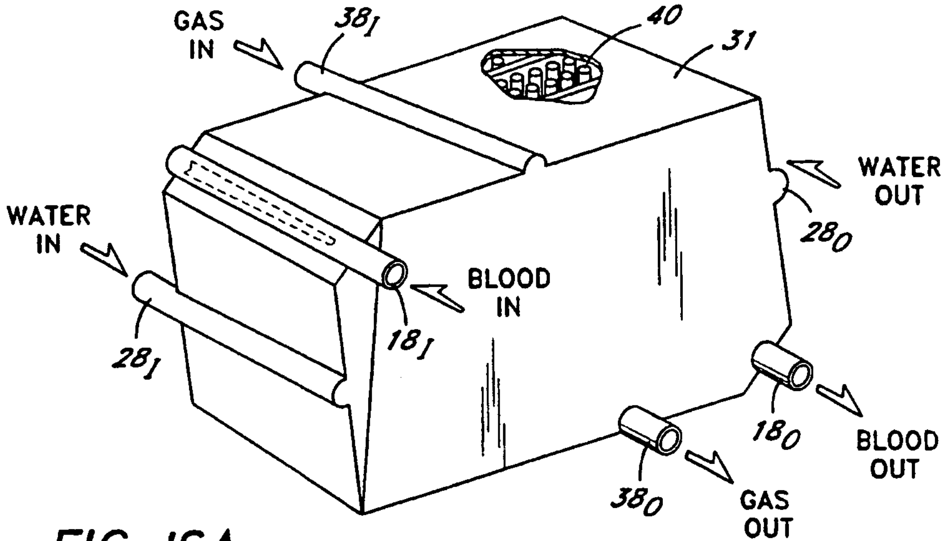


FIG. 16A

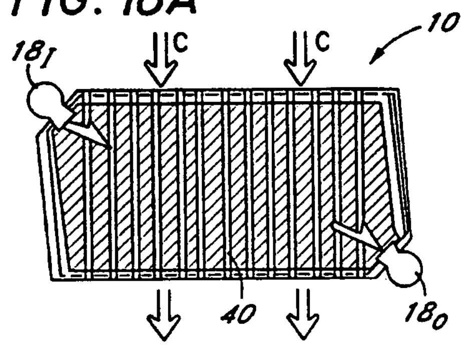


FIG. 16B

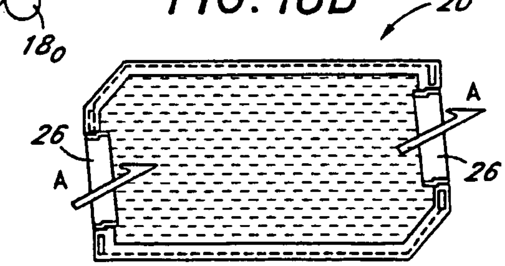


FIG. 16C

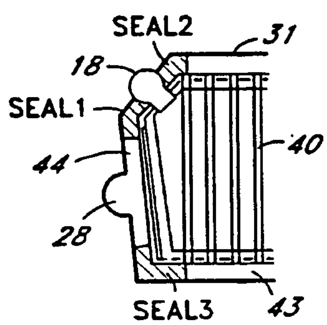


FIG. 17A

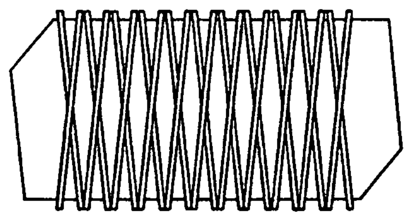


FIG. 17B

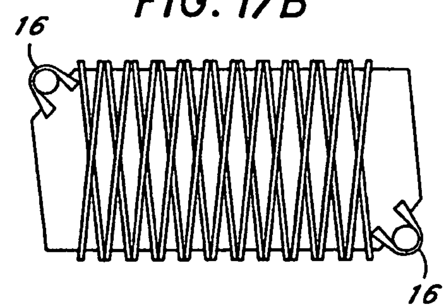


FIG. 17C

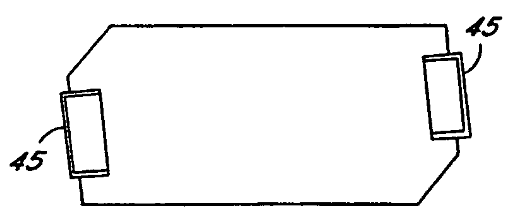


FIG. 17D

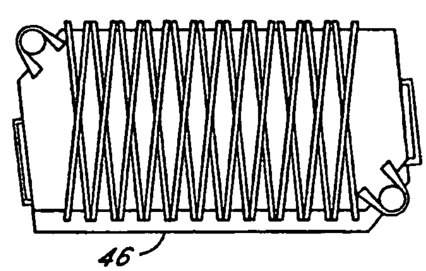


FIG. 17E

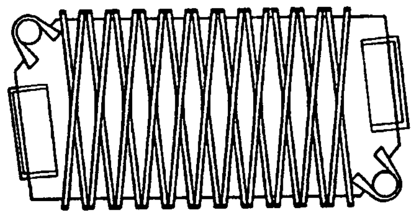


FIG. 17F

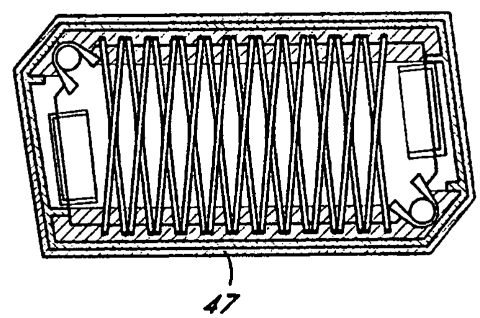


FIG. 17G

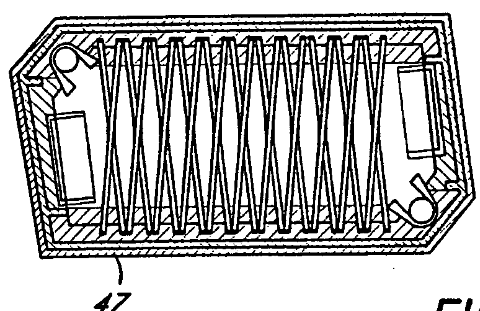


FIG. 17H

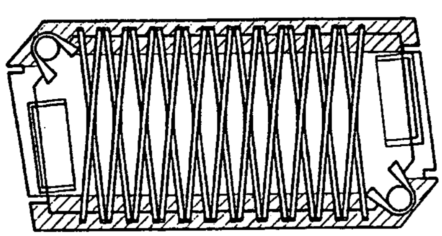


FIG. 17I

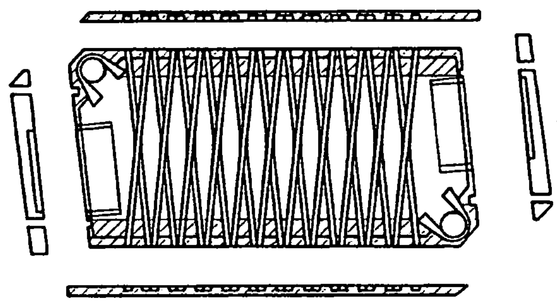


FIG. 17J

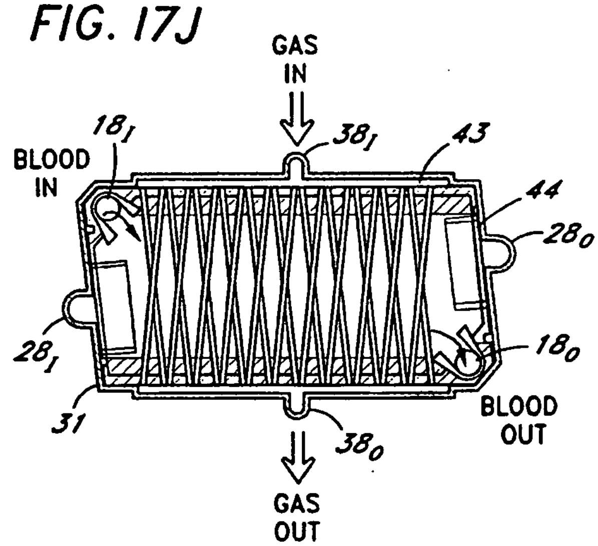


FIG. 18A

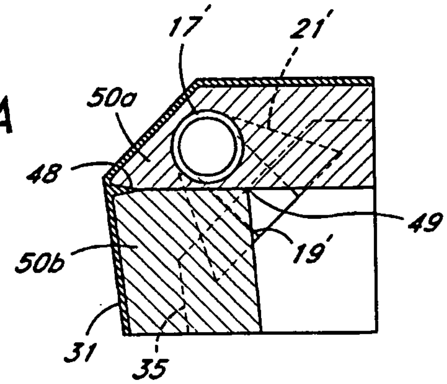


FIG. 18B

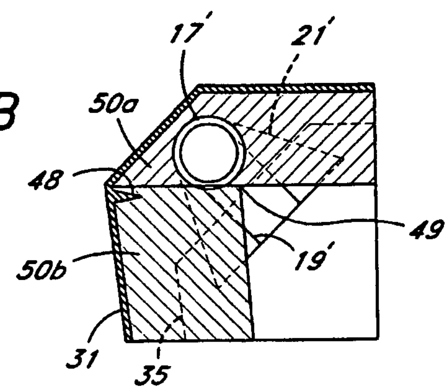


FIG. 18C

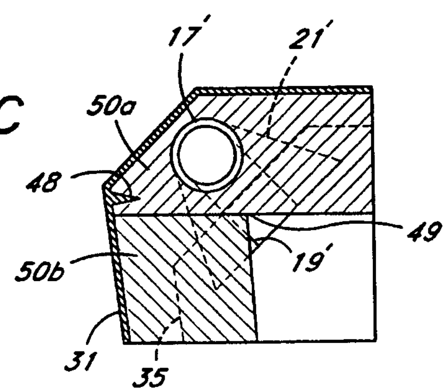


FIG. 19A

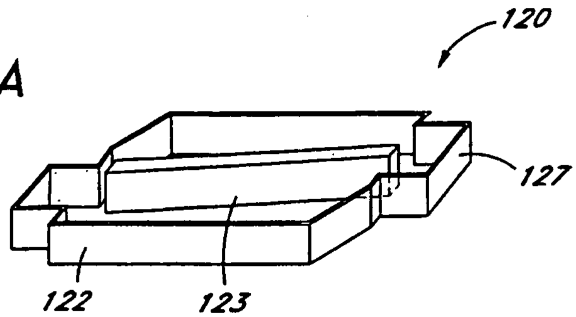


FIG. 19B

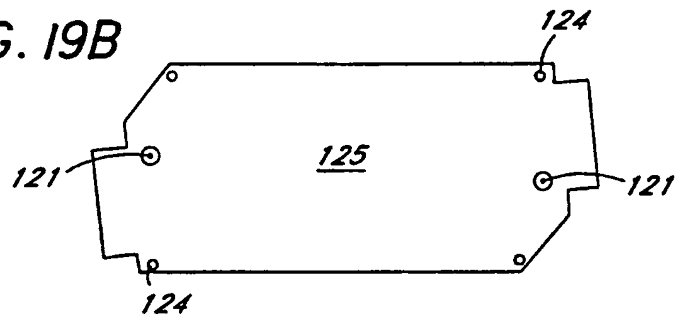


FIG. 19C

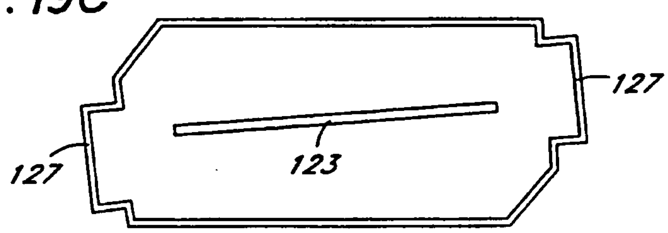


FIG. 19D

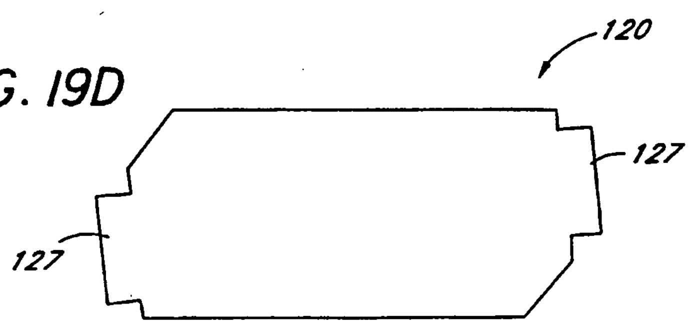


FIG. 20

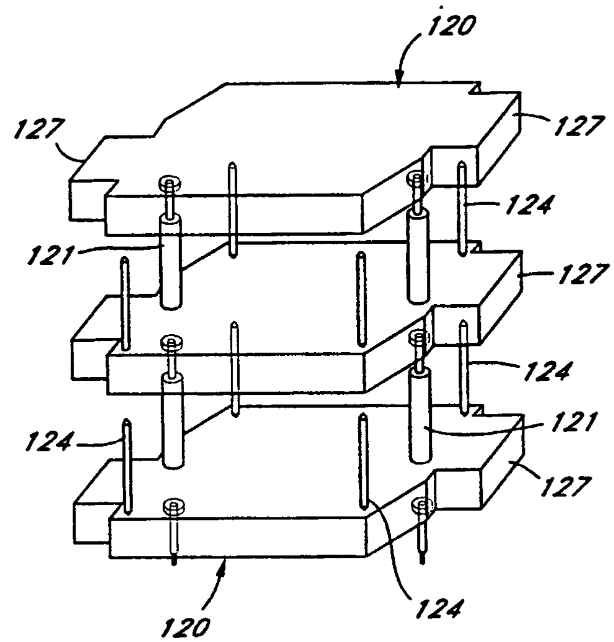


FIG. 21

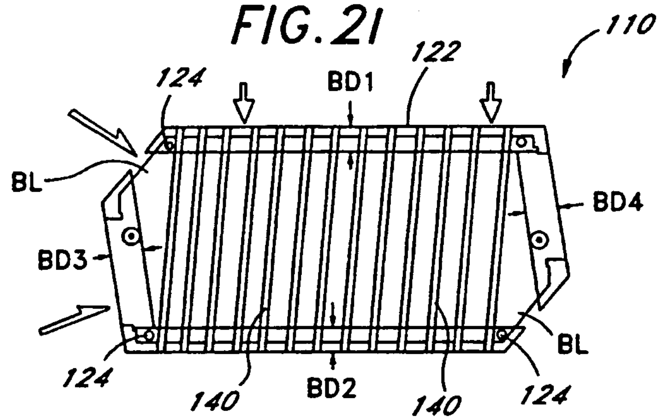


FIG. 22

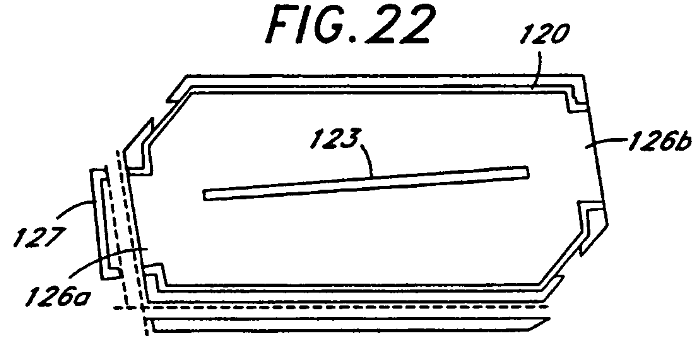


FIG. 23

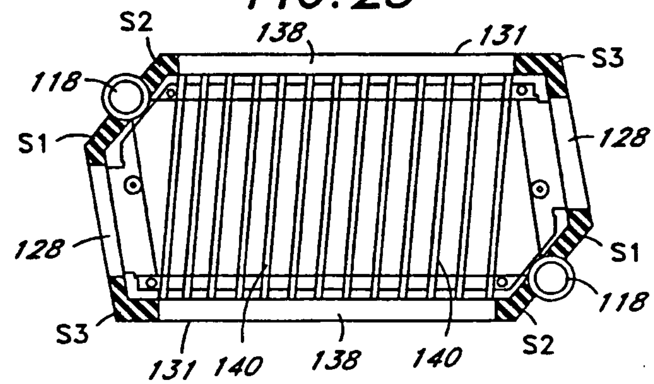
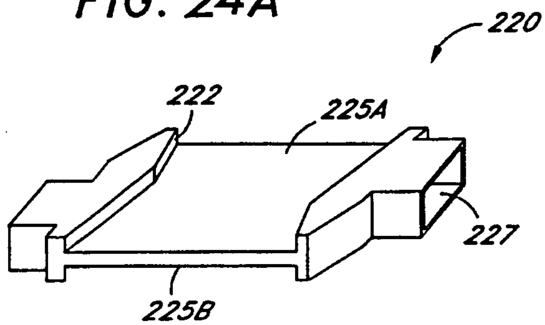


FIG. 24A



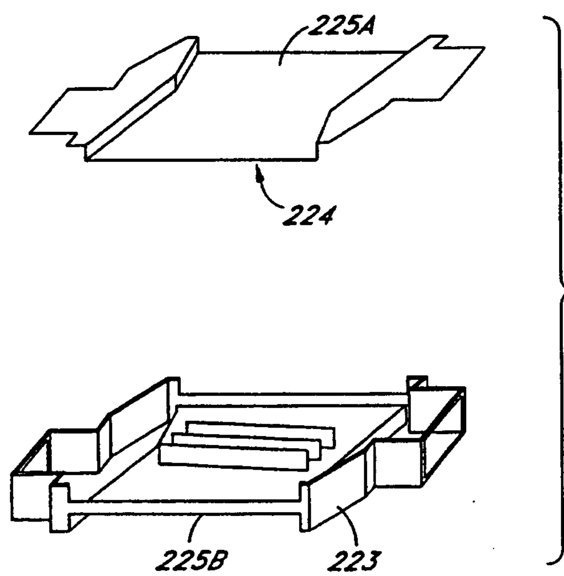


FIG. 24B

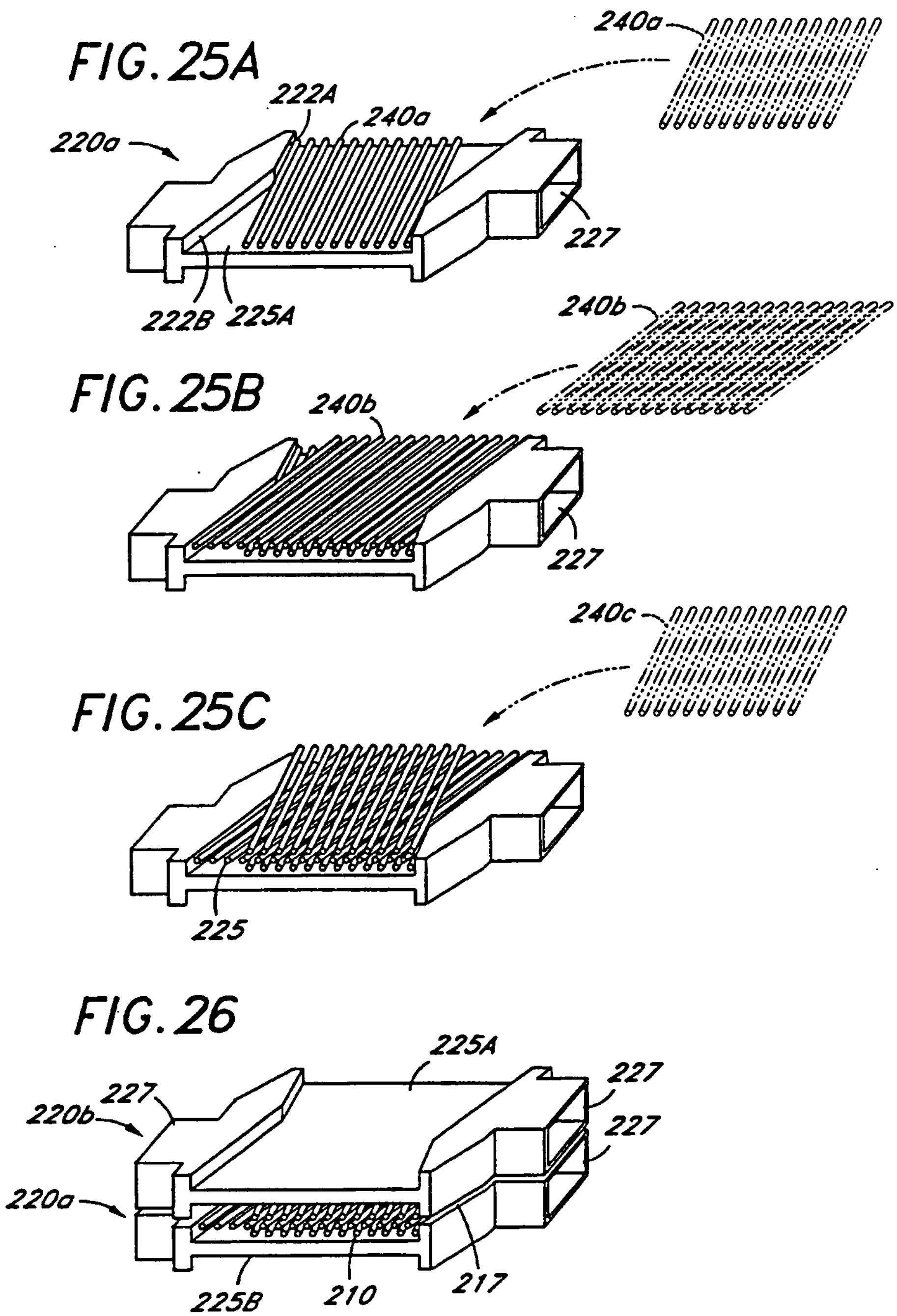


FIG. 25A
240a
222A
240a
220a
227
222B
225A
FIG. 25B
240b
240b
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FIG. 25C
240c
225
FIG. 26
225A
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227
220b
227
220a
225B
210
217

FIG. 27

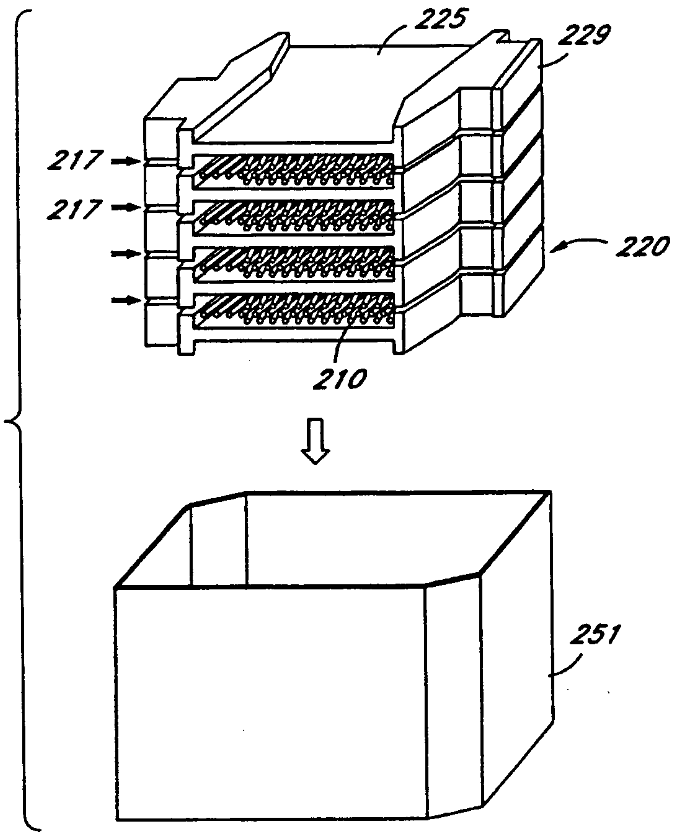


FIG. 28

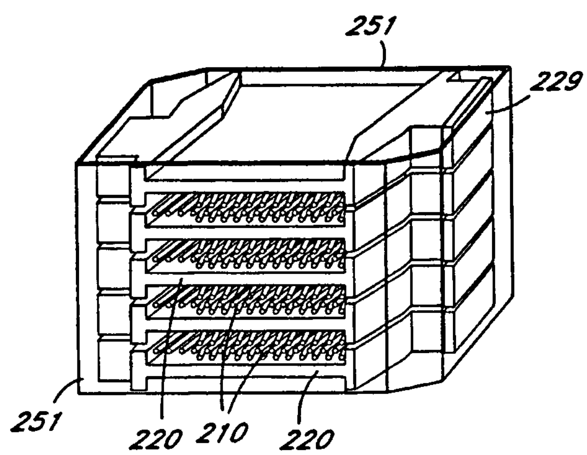


FIG. 29

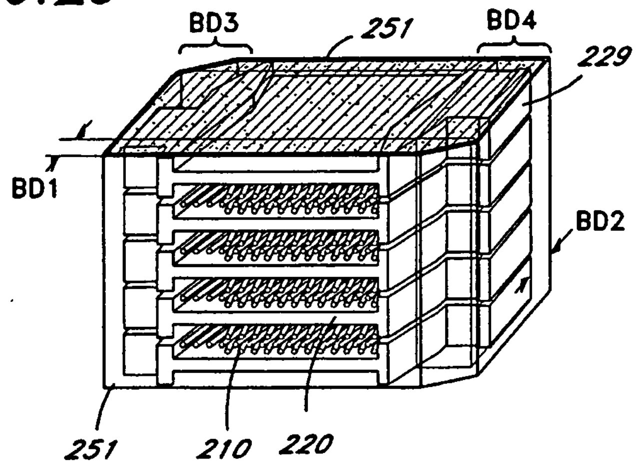


FIG. 30

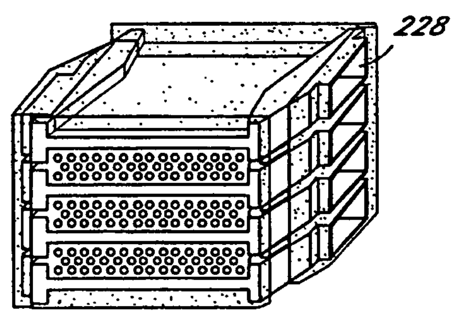


FIG. 31

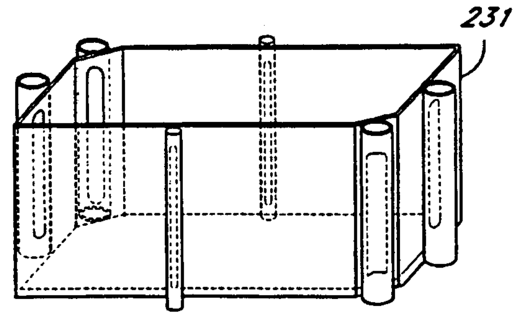


FIG. 32

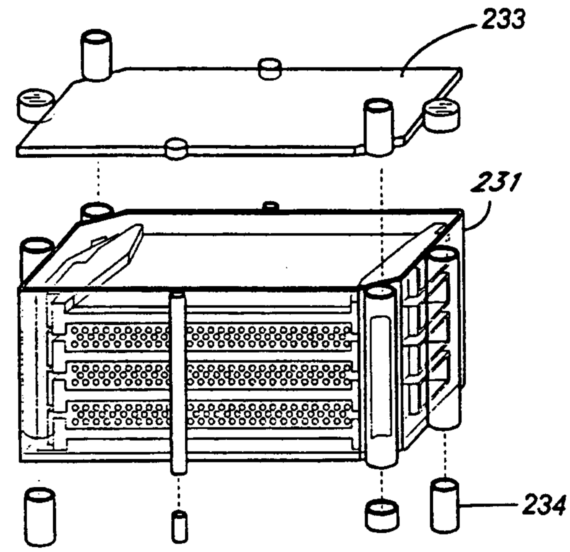


FIG. 33

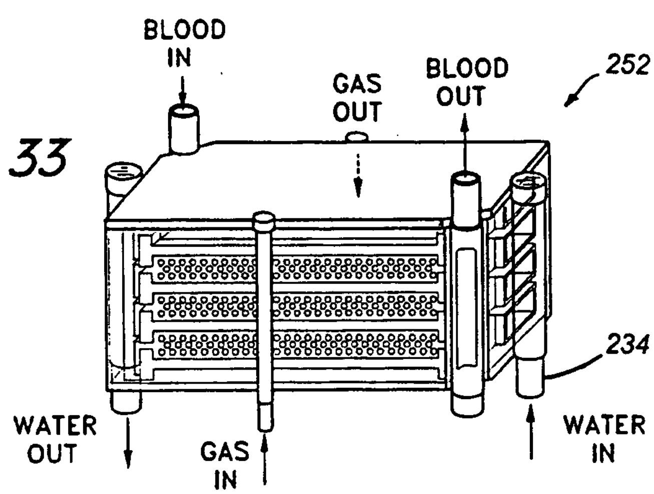
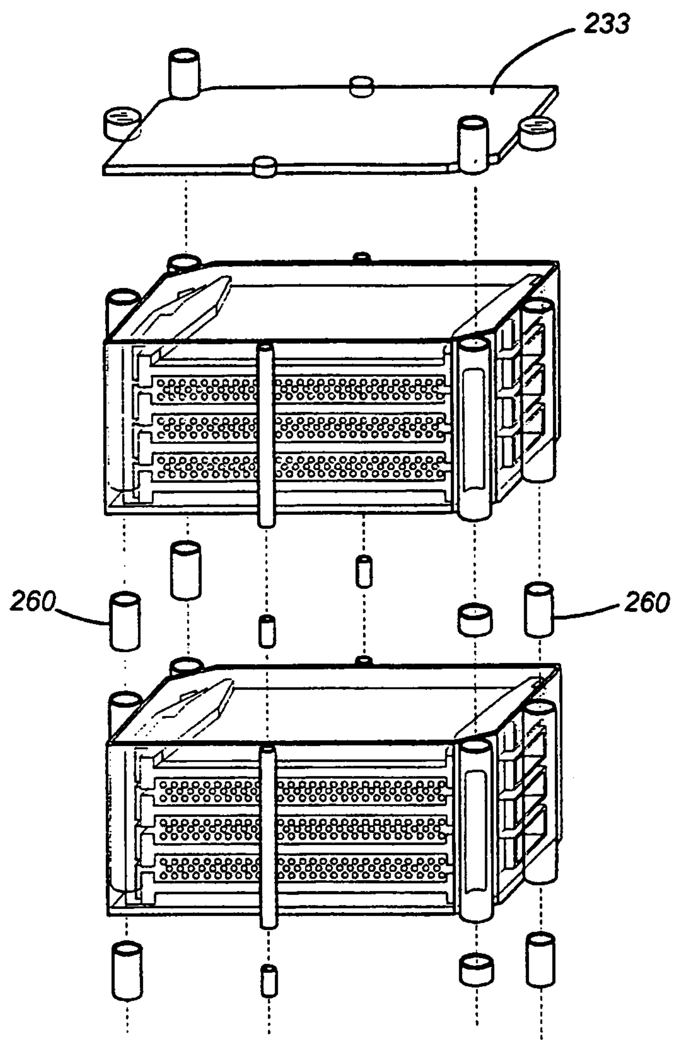


FIG. 34A



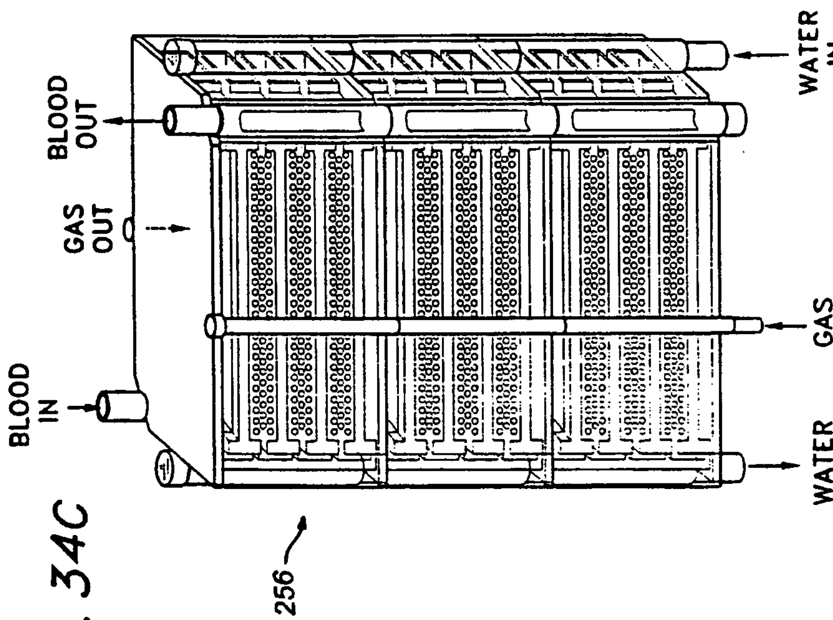


FIG. 34C

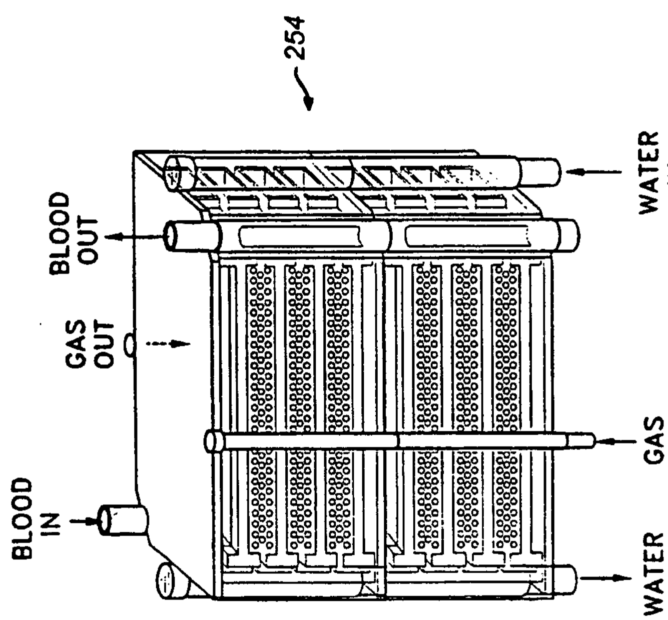


FIG. 34B

FIG. 35A

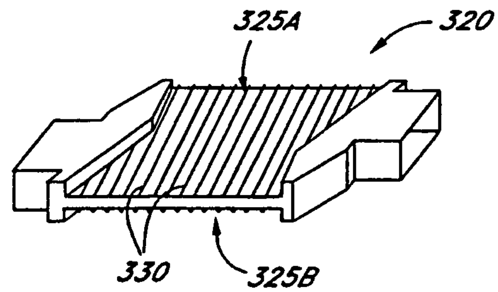
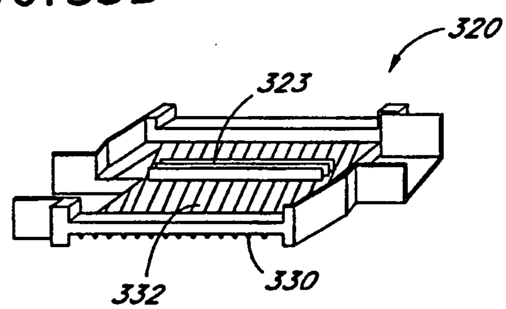


FIG. 35B



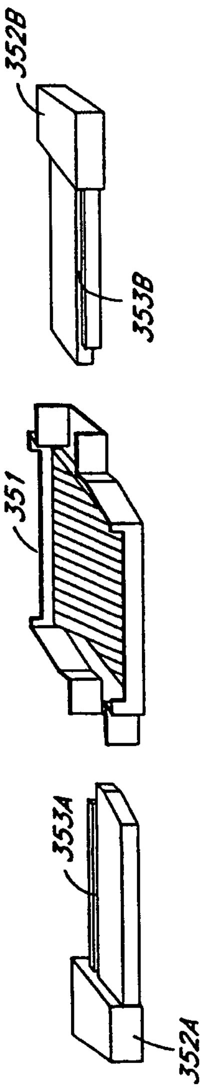


FIG. 36A

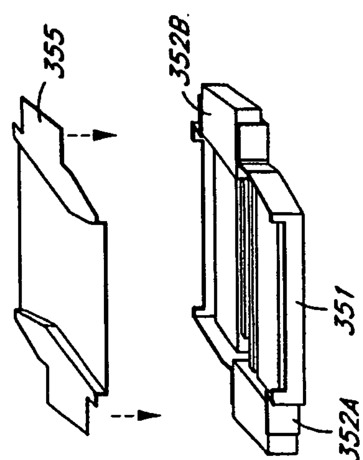


FIG. 36B

FIG. 36C

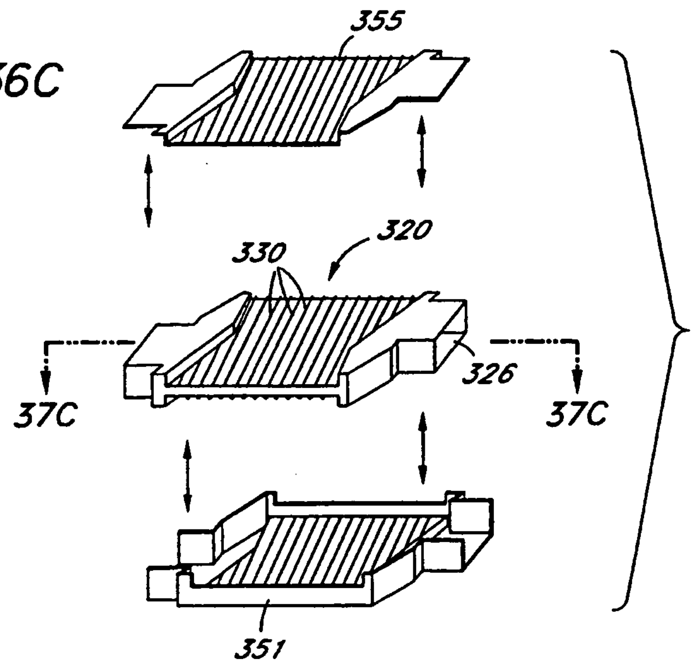
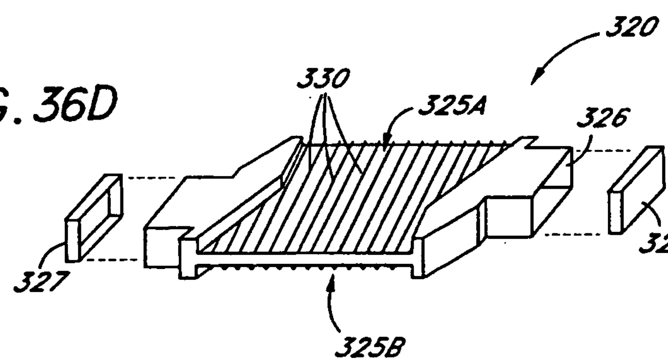


FIG. 36D



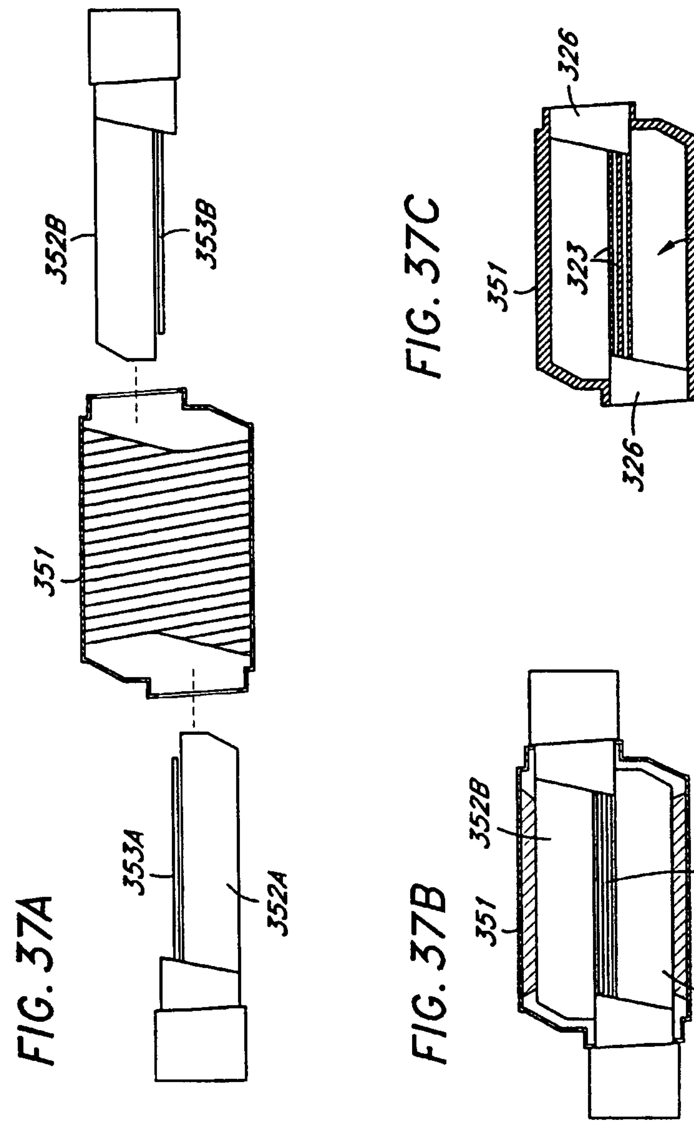


FIG. 37A

FIG. 37B

FIG. 37C

FIG. 38

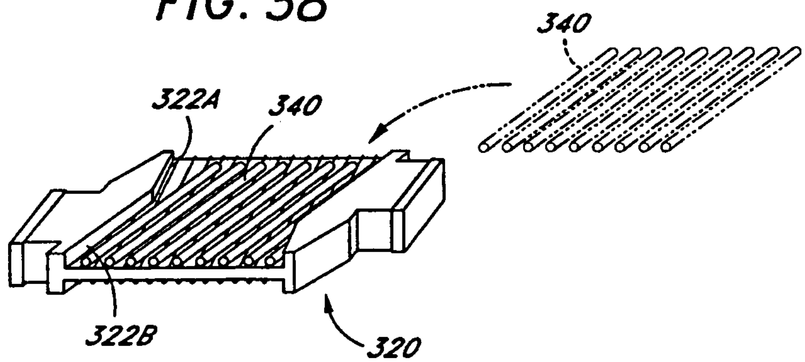


FIG. 39

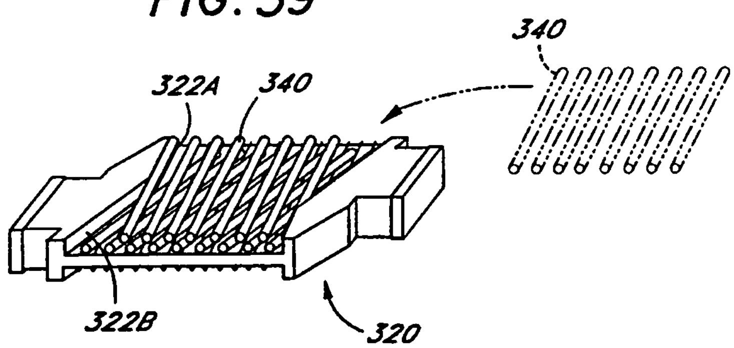


FIG. 41

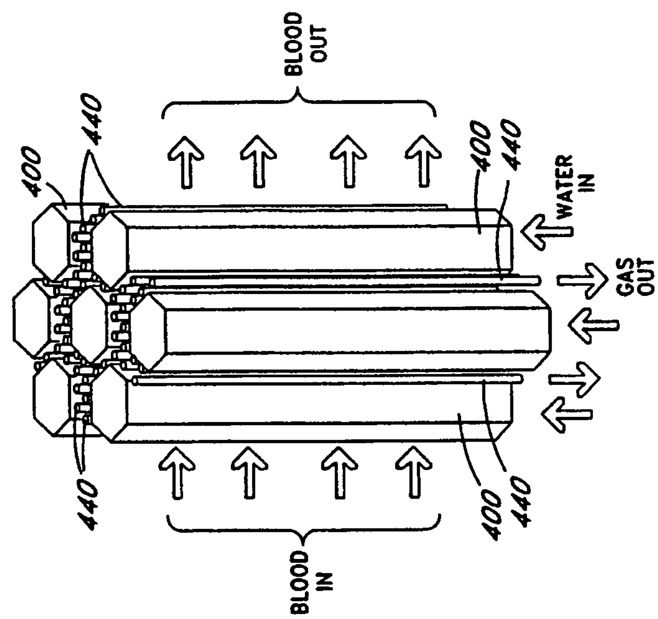

400
440
BLOOD OUT
400
440
WATER IN
GAS OUT
440
400
440
BLOOD IN

FIG. 40

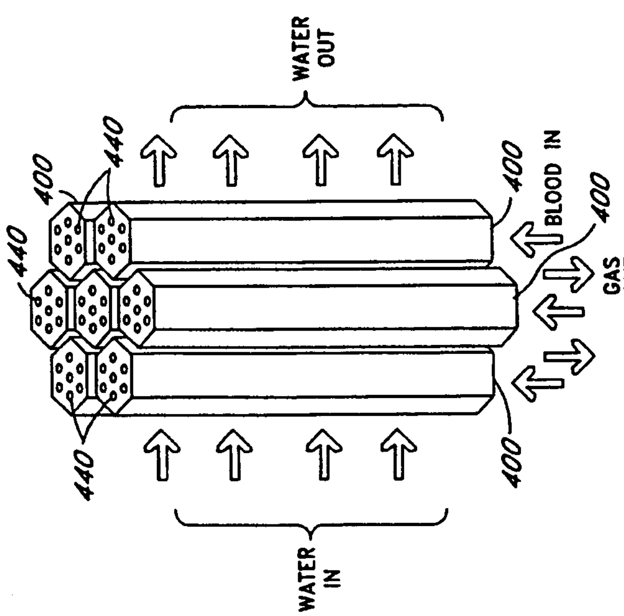

440
400
440
WATER OUT
400
BLOOD IN
400
GAS OUT
440
400
WATER IN

FIG. 43

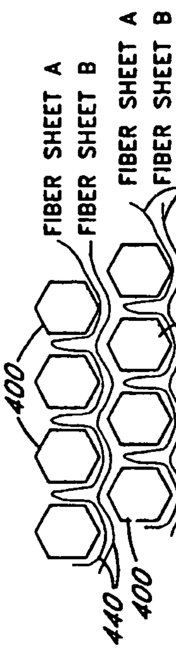

FIBER SHEET A
FIBER SHEET B
FIBER SHEET A
FIBER SHEET B
440
400
400
400
400
440

FIG. 42

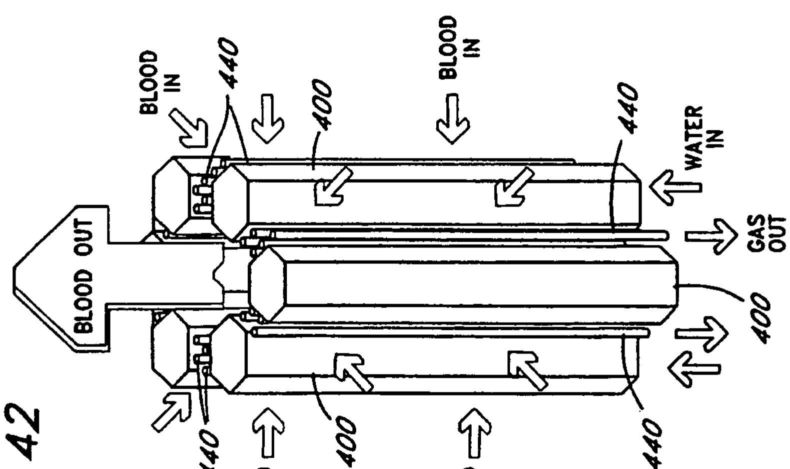

BLOOD OUT
BLOOD IN
BLOOD IN
BLOOD IN
BLOOD IN
440
400
440
400
WATER IN
GAS OUT
400
440
440
400

FIG. 44A FIG. 44B FIG. 44C

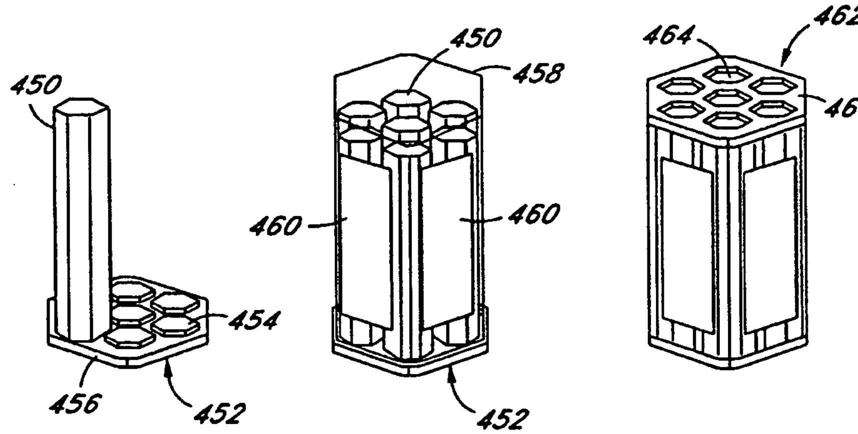


FIG. 44D

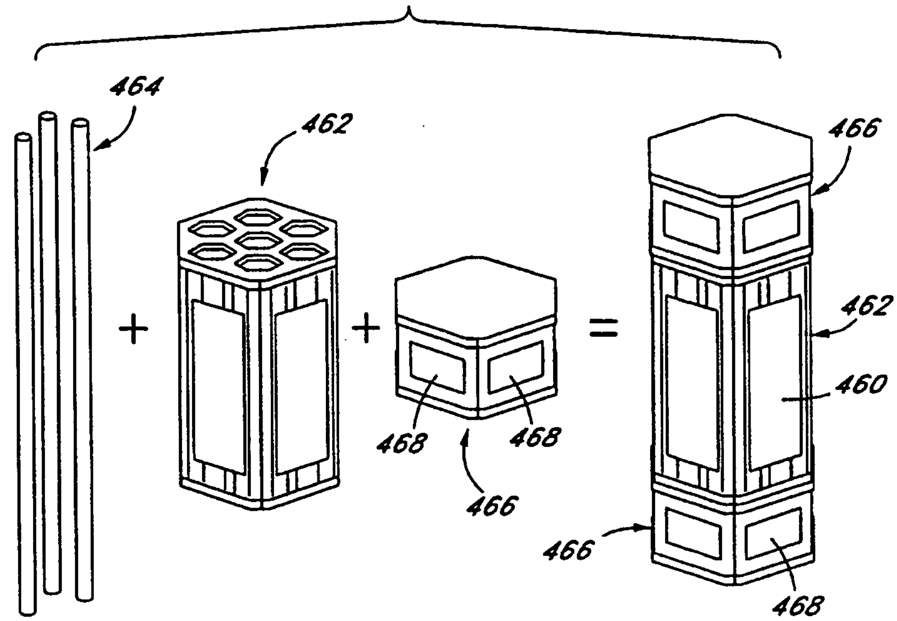


FIG. 44F

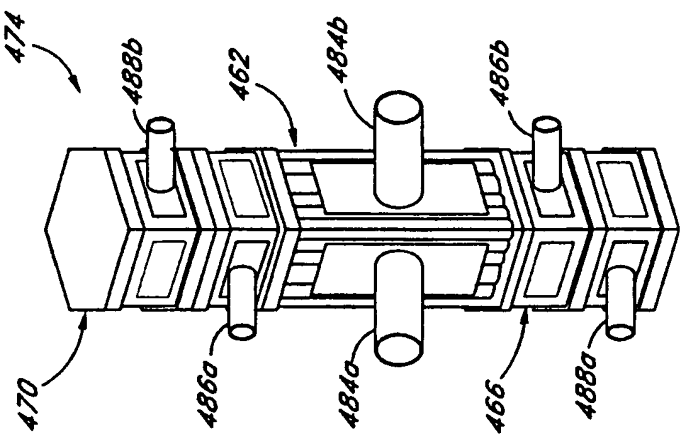


FIG. 44E

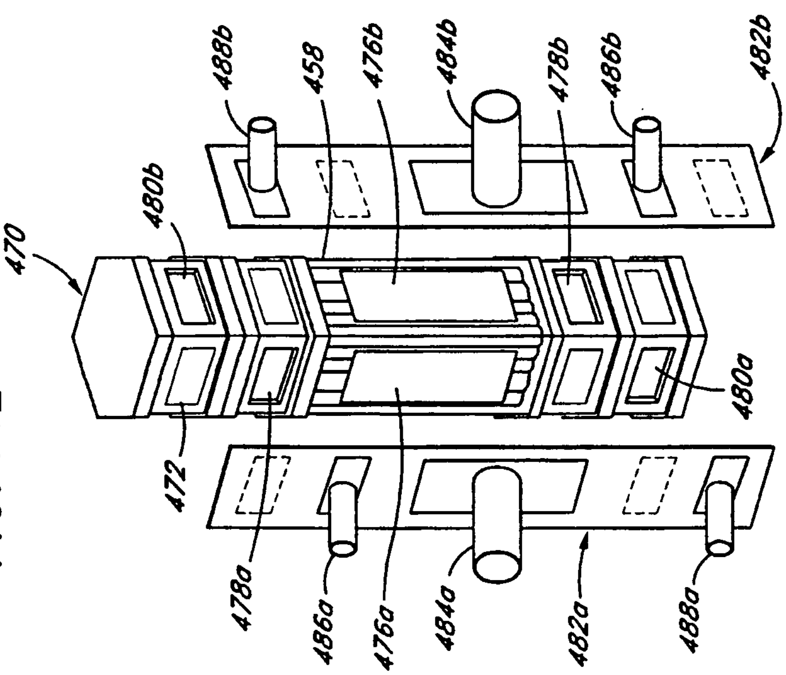


FIG. 45A

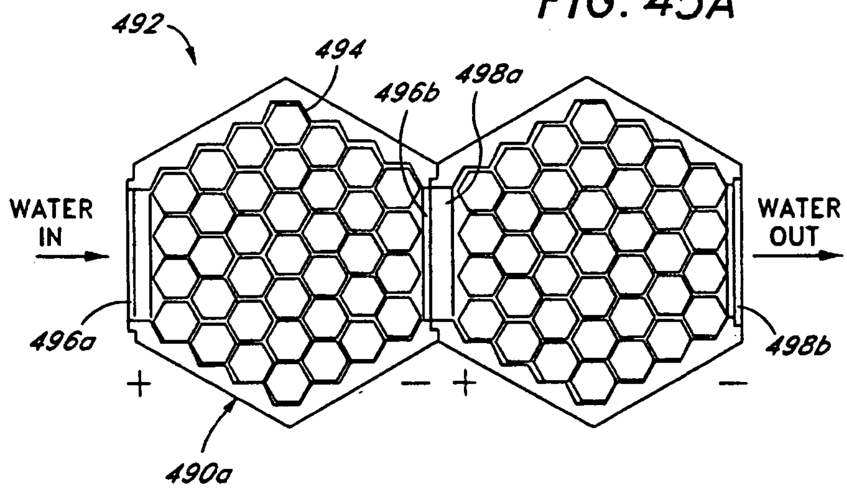


FIG. 45B

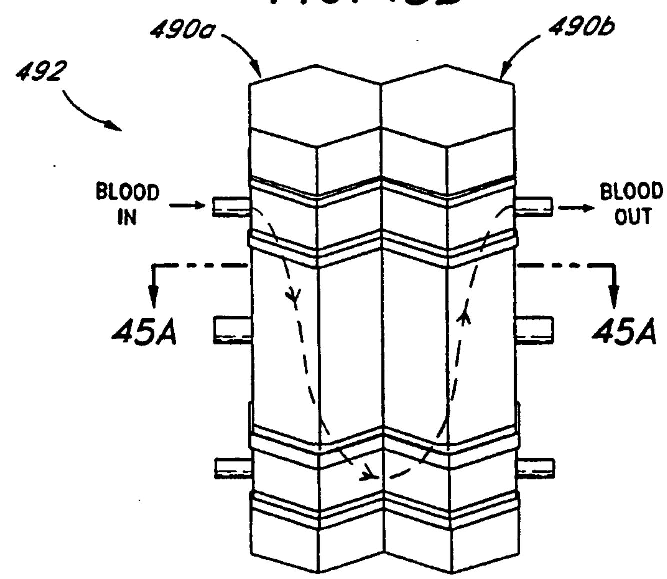


FIG. 46A

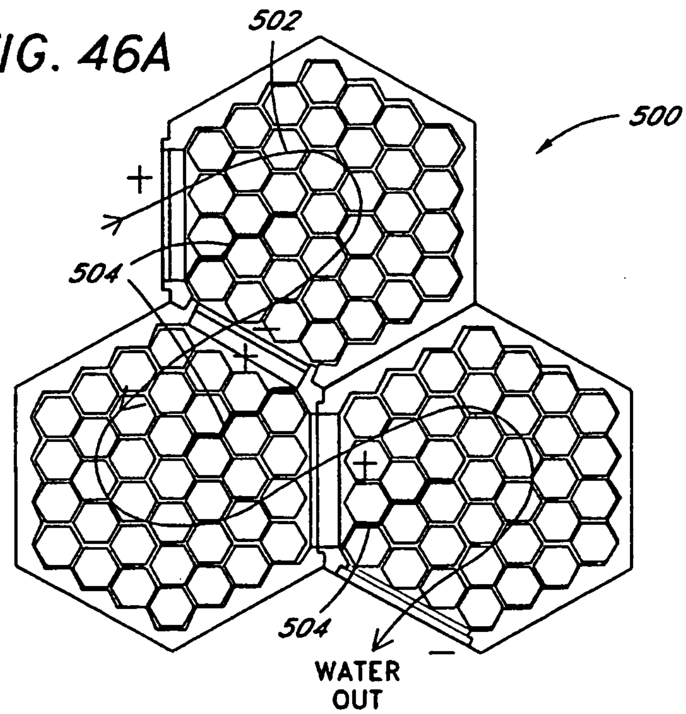


FIG. 46B

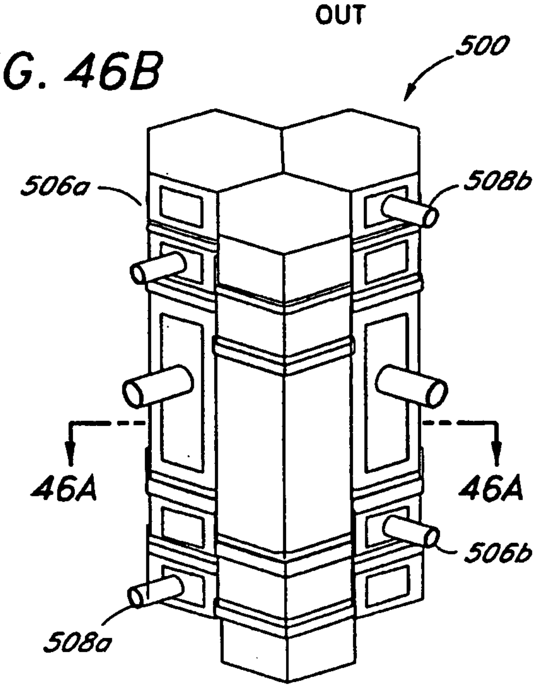


FIG. 47A

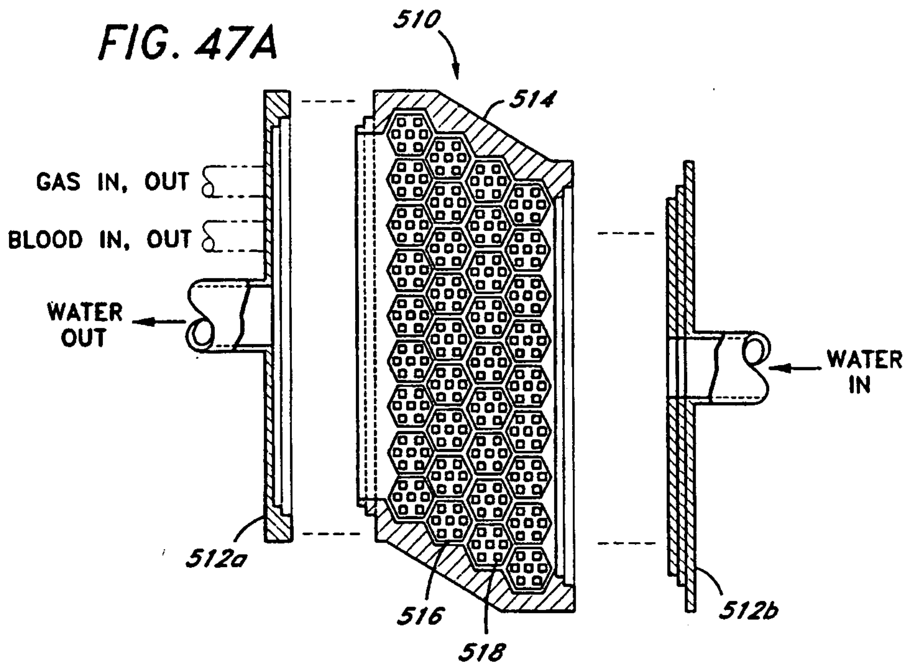


FIG. 47B

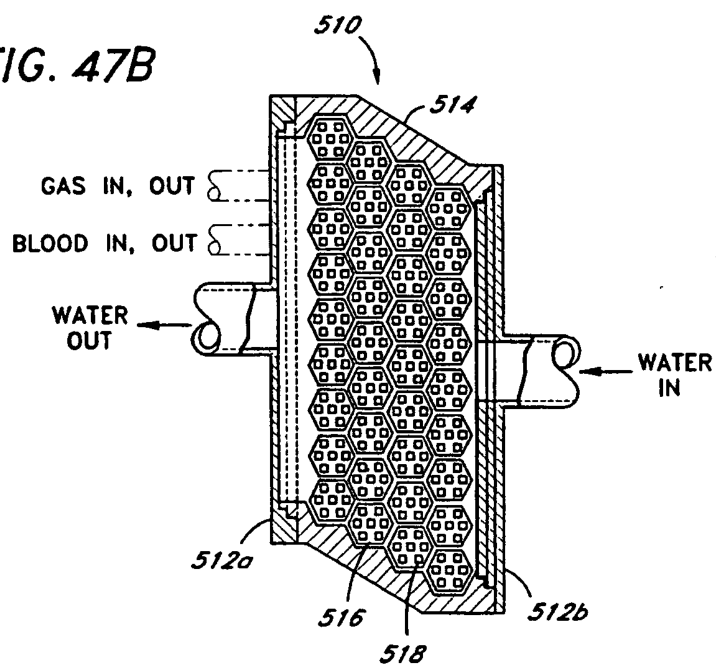


FIG. 48A

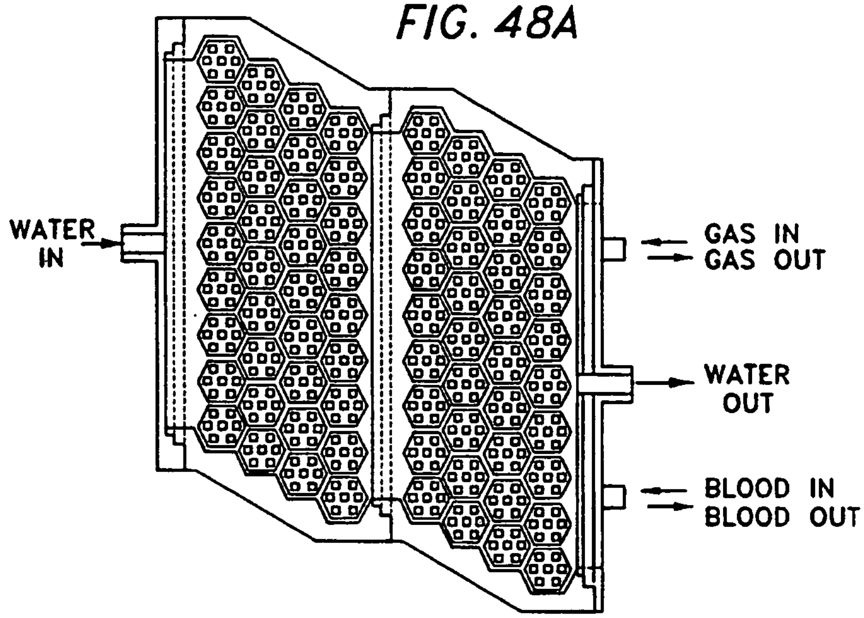
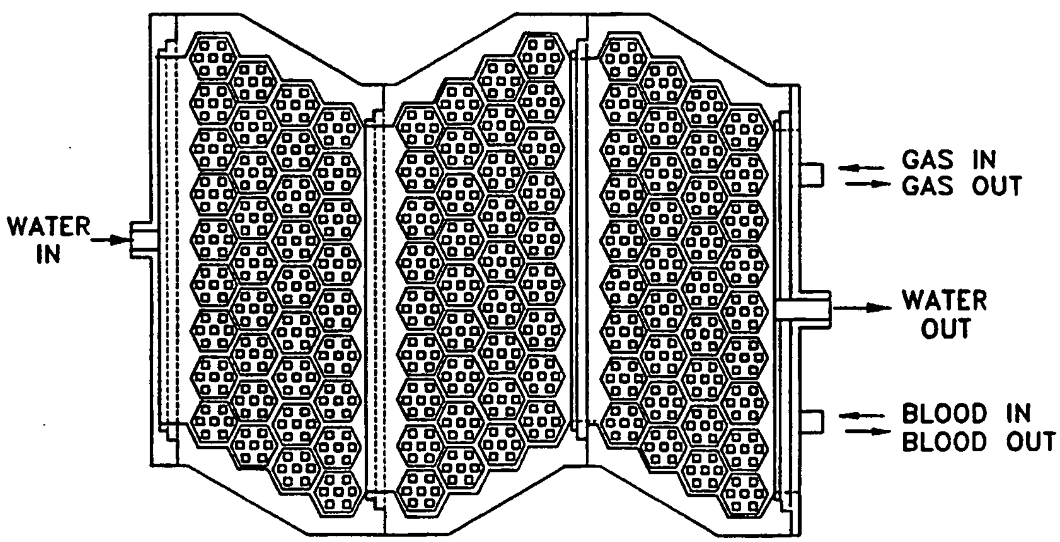


FIG. 48B



INTERNATIONAL SEARCH REPORT

In. .ational Application No
PCT/US 99/07642

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B01D63/04 A61M1/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B01D A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 534 386 A (OEDEKOVEN BERNWARD) 31 March 1993 (1993-03-31) column 6, line 23 - line 37 figures 4,5	1,17, 46-48
A	EP 0 264 696 A (AKZO NV) 27 April 1988 (1988-04-27) column 5, line 50 - column 6, line 18	1,17,47

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
23 August 1999	30/08/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Vereecke, A

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INTERNATIONAL SEARCH REPORT

Information on patent family members

In. ational Application No
PCT/US 99/07642

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AT 161195 T	15-01-1998
		DE 59209070 D	29-01-1998
EP 0264696 A	27-04-1988	DE 3733542 A	14-07-1988
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